

AS/EN/JISQ 9100:2016 EVALUATION GUIDANCE MATERIAL

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1.0 Introduction

This document provides general guidance for use by audit teams when executing the audit process described by the 9101:2016 standard, when conducting 9100:2016 audits.

This guidance is not intended to add to, subtract from, or in any way modify the stated requirements, but to provide examples and thought stimulation i.e. “things to consider”, when asking questions and identifying objective evidence.

NOTES:

- The guidance contained within this document can also be useful when preparing and planning an audit during the certification cycle.
- Acceptable means of compliance are not limited to those items listed in this document.
- Any issues identified during audits are to be documented against 9100:2016 requirements.
- 9100:2016 clause 0.3 describes the process approach developing, implementing, and improving the effectiveness of a Quality Management System
- 9101:2016 clause 0.2 describes the process approach when evaluating an organizations QMS
- Further ISO guidance is also available as follows:
 - Process approach for management systems - ISO/TC 176/SC2/N544R3
 - Application of ISO 9001:2015 management system - ISO Technical Specification ISO/DTS 9002
- This document does not provide guidance for the additional requirements defined by 9110 and 9120.

2.0 Process Auditing Approach

2.1 General Approach

When evaluating an organization's QMS, there are basic questions that should be asked of every process, for example:

- Is the process appropriately determined?
- Is the process identified and appropriately defined, including for example process inputs, outputs, resources and controls?
- Are Process Owner and Process User responsibilities assigned?
- Is the process implemented and maintained?
- Is the process effective in achieving the desired results?

Other questions could include:

- What is the process?
- What is it trying to achieve?
- Who is the customer of the process?
- Does the process address applicable customer specific requirements?
- Are Process User competencies identified?
- Is the process operating, as defined?
- What is the desired level of performance?
- Have process performance targets been established, including those specified by the customer?
- Have process measures (e.g. KPIs) been established and are mechanisms in place to collate and analyze the data?
- What is the current level of performance?
- Is process performance regularly reviewed by top management?
- Where performance is not being achieved, are improvement plans in place?

2.2 Specific Approaches

There are a number of specific audit approaches that can be built into the audit plan to provide focus on key elements of the QMS, including for example:

2.2.1 Customer Focus

The audit team should determine that customer satisfaction is being evaluated and appropriate actions are taken by the organization based on available performance information (e.g., nonconformity data, corrective action requests, results of satisfaction surveys, complaints regarding product quality, OTD, service provision, responsiveness to customer and internal requests) provided by the organization's customers (e.g., scorecards, report cards).

2.2.2 Organizational Leadership

The Interview with top management should be used to evaluate:

- Establishment and continued relevance of the organization's quality policy and objectives;
- Establishment of performance measures aligned to quality objectives;
- QMS development, implementation, and continual improvement;
- Top management commitment;
- QMS performance and effectiveness;
- Performance to customer expectations (e.g., supplier rating, scorecard, audit results); and
- Actions taken to address issues that are not meeting customer performance expectations.

2.2.3 QMS Performance and Effectiveness

The audit of QMS performance and effectiveness should include a review of the following:

- Processing of customer complaints, customer feedback data (e.g., periodic performance reports received from customers), and other relevant customer data (e.g., results of customer surveys);

- Results and actions from internal and external audits of the QMS, including their associated records;
- Stakeholder feedback (e.g., feedback from regulatory authorities or other interested parties);
- Processing of process/product nonconformities, including review of associated corrective actions and evaluation on the effectiveness of actions taken;
- Processing of preventive actions, including evaluation on the effectiveness of actions taken;
- Management review conduct, including associated records (e.g., process inputs/outputs, actions taken);
- Internal performance monitoring, measurement, reporting, and reviews against stakeholder and internal performance objectives and targets, including continual improvement activities and associated records;
- Organization's current performance against targets, including customer specific targets and associated records of applicable actions taken where targets are not being met; and
- The status and effectiveness of the organization's process performance improvement activities and their outcomes related to product quality.

2.2.4 Process Management

The audit team should conduct QMS audits using a method that focuses on process performance and effectiveness; this ensures that priority is given to the following:

- Reviewing the organization's processes, their sequence and interactions, the identification of functions and assignment of responsibilities, and performance against requirements and defined measures, with focus on processes that directly impact the customer;
- Reviewing the process for validation and approval of processes and process changes;
- Reviewing the availability of resources and information required to operate and support associated activities, including appropriate training and competency of personnel;
- Reviewing the process-based management techniques, including the examination of process measures (e.g., quality, tact time, cycle time, output effectiveness, control limits, process capability determination);
- Reviewing plans in place to ensure performance objectives/targets are monitored, measured, and analyzed in order to realize the planned activities and achieve the planned results (e.g., verify performance information availability, percentage of nonconforming parts/products, percentage OTD);

- Reviewing applicable action taken when objectives/targets are not met to promote continual improvement; and
- Pursuing audit trails addressing customer concerns or requests for corrective actions, performance against objectives, and relevant process controls.

NOTE:

The audit team should audit processes to sufficient depth and detail to evaluate if the organization's processes are capable of meeting planned results and performance levels, including applicable customer specific targets.

2.2.5 Continual Improvement

The audit team should evaluate the organization's interrelated processes and activities for continual improvement of the QMS, its processes, their conformity, and effectiveness in order to:

- Ensure focus on issues that are important to the organization, their customers, and regulatory authorities; and
- Determine the effectiveness of an organization's approach to continually improving process performance.

NOTE:

The organization should be able to demonstrate that they have a structured approach to achieve continual improvement of the QMS and its processes.

3. Audit Considerations

This section looks at the requirements of 9100:2016 by clause number and provides examples of typical evidence that can be sought and considered by the audit team during execution of the audit plan.

Clause #	Considerations
4.	CONTEXT OF THE ORGANIZATION
4.1	<p>Understanding the Organization and its Context Things to consider:</p> <ul style="list-style-type: none"> • Policy statement(s) regarding the organizations purpose and strategic direction • Individual strategy or tactical plan documents written to underpin the organizations policies and provide a road map to achieve its future goals • Records of meetings where context is routinely discussed and monitored, e.g. as part of the structured management review process or within each of the respective function of the organization (Purchase, HR, Engineering, Sales, Finance etc.) • Structured risk assessment of External and Internal issues. • Use of PEST (Political, Economic, Social, Technological), PESTLE (Political, Economic, Social, Technological, Legal, Environmental) and SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis tools • Documented information that describes the context of the organization that could be included as part of a single source of documented information (sometimes referred to as a Quality Manual) <p>Sources of information relating to External and Internal issues could include:</p> <p>External:</p> <ul style="list-style-type: none"> • Reports relating to competitive environment, new technologies, new markets, customer expectations, supplier intelligence, economic conditions, political considerations, investment opportunities, social factors etc. • Identification of factors relating to changing legislation and regulations, including environmental impact • Feedback relating to product/service performance and lessons learned • Register of identified external risks and their treatment <p>Internal:</p> <ul style="list-style-type: none"> • Structure of the organization, identification of roles and responsibilities and arrangements for governance

	<ul style="list-style-type: none"> • Reports' showing how well the organization is performing • Statements relating to the organizations mission, vision and core values • Emphasis placed upon business ethics and organizational codes of conduct • Feedback obtained from employees, e.g. employee survey results • Information systems and the mechanism for capturing and sharing knowledge and lessons learned • Organizational capability studies, identification of load/capacity and resource requirements to achieve demand • Register of identified internal risks and their treatment
4.2	<p>Understanding the Needs and Expectations of Interested Parties</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Use of brainstorming techniques to identify relevant external and internal interested parties, e.g. customers, partners, end users, external providers, owners, shareholders, employees, trade unions, government agencies, regulatory authorities, local community • Use of surveys, networking, face-to-face meetings, association membership, attending conferences, lobbying, participation in benchmarking, etc., in order to gain stakeholder information and their requirements • Stakeholder mapping to determine importance using the four-quadrant method (power/influence versus interest/importance grid). • Use of RACI (Responsible, Accountable, Consulted, Informed) method to determine level of stakeholder engagement • Flow down and capture of requirements relevant to the QMS defined in contracts, orders, statements of work, terms of business etc. • Records of meetings where interested parties and their requirements are routinely discussed and monitored, e.g. as part of the structured management review process, or within each of the respective function of the organization (Purchase, HR, Engineering, Sales, Finance etc.) <p>NOTE: The organization determines the relevant interested parties and their requirements relating to the activities of the organization and the impact on their QMS</p>
4.3	<p>Determining the Scope of the Quality Management System</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization evaluation of: <ul style="list-style-type: none"> ○ External and internal issues (see 4.1) ○ Requirements of relevant interested parties (see 4.2) ○ Its products and services • Consideration of boundaries and applicability of the QMS can include:

	<ul style="list-style-type: none"> ○ Range of products and services ○ Different sites and activities ○ External provision of processes, products and services ○ Common support provided by centralized functions ○ Infrastructure of the QMS such as distribution, accessibility, different layers (process, procedure, instructions, site specific requirements) • Document written and maintained by the organization that describes the scope of the QMS, including: <ul style="list-style-type: none"> ○ A statement of the types of products and services covered ○ Assessment of the applicability of the 9100 requirements ○ Justification for any 9100 requirement(s) that is/are determined as 'not applicable' • Alignment between the documented scope of the organization's QMS and their agreed scope of certification
4.4	Quality Management System and its Processes
4.4.1	<p>Things to consider:</p> <ul style="list-style-type: none"> • Identification of the processes needed for the QMS, including their sequence and interaction, e.g. process framework, process model, process groupings, process flow diagram, process mapping, value stream mapping, Turtle diagrams, SIPOC (Supplier, Input, Process, Output, Customer) charts, process cards • Information needed to ensure effective operation and control of the processes, e.g. defined process requirements (shall), good practice (should), defined roles, required competencies, associated training, guidance material • Expected inputs and outputs from each of the identified processes, together with assignment of responsibilities and authorities e.g. Process Owner, Process Champion, Lead Process User, Process User. • Criteria and method to ensure effective operation and control of the identified processes, e.g. process monitoring indicators, process performance indicators, target setting, data collection, performance trends, internal/external audit results • Arrangements for governing the processes e.g. process owner reviews, process councils, flight deck/dashboards, risks and opportunities relating to the process, resource needs, user training/competency, continual improvement initiatives, frequency of reviews, agenda, minutes, actions • Organization approach towards continual improvement and action taken when process performance is not meeting intended results • Capture of customer, statutory and regulatory requirements and the method used to build these into the organizations QMS, e.g. requirements capture, gap analysis, requirements embedded into the process definition, assigned contract assurance instructions, formal links to information, use of specified documentation

4.4.2	<p>Things to consider:</p> <ul style="list-style-type: none">• Documentation created and maintained by the organization to support the operation of the processes, e.g. manuals, expositions, handbooks, documented procedures, work instructions, guidance material, data cards, physical samples, IT systems (including intranet and internet), universal/bespoke software, templates, forms• Documentation identified and retained by the organization to show that processes are carried it as planned, e.g. physical hard copy records, electronic media (data servers, hard drives, compact discs, flash drives etc.)• Specific documentation created and maintained by the organization that includes a description of relevant interested parties (see 4.2), scope of the QMS including boundaries and applicability (see 4.3), description of the processes needed for the QMS together with their sequence, interaction and application and assignment of responsibilities for the processes. <p>NOTE: The organization can compile this specified information together in a single repository and may refer to it as a Quality Manual.</p>
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Clause #	Considerations
5.	LEADERSHIP
5.1	Leadership and Commitment
5.1.1	<p>General</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Top management commitment towards the QMS to demonstrate that they have a presence in the organization, provide direction, lead by example, make decisions and have: <ul style="list-style-type: none"> ○ Taken accountability for the effectiveness of the QMS e.g. established measures, system/process performance monitoring, management review, realization of planned activities, achievement of planned results and taking action when process performance is not meeting intended results ○ Established and maintain the quality policy and objectives aligned to the strategic direction e.g. context of the organization, external/issues (see 4.1) ○ Integrated quality requirements into the organizations business processes e.g. system architecture, business model, process model, organization footprint, functional alignment (Engineering, Purchasing, IT, Finance, HR etc.) ○ Promoted the process approach and risk based thinking e.g. process modeling, process mapping, inputs, outputs, activities, interactions, interfaces, resources, controls, risk management (identification, severity, ownership, treatment etc.) ○ Supported process owners in their process management activities e.g. deployment, governance, process evaluation, process improvement ○ Enabled the resources (including people) required for an effective QMS e.g. resource planning, workload, priorities, constraints, balance, organization flexibility, business benefits, organization growth ○ Communicated the importance of conformity to the QMS and effective quality management e.g. meetings, briefs, e-mail, intranet, campaigns, roadshows, focused training, voice of the regulator/customer, consequence of nonconformity ○ Created an environment for continual improvement e.g. <ul style="list-style-type: none"> ▪ Proactive - product/service/process improvement initiatives, improvement projects, waste reduction (lean), process re-engineering, cost reduction etc. ▪ Reactive - acting on process performance results, audit findings, complaints, escapes etc.

	<ul style="list-style-type: none"> ○ Supported other relevant management roles e.g. organization hierarchy, trust, empowerment, responsible delegation, coaching, sharing knowledge, removing barriers, route to escalation
5.1.2	<p>Customer Focus Things to consider:</p> <ul style="list-style-type: none"> • Top management commitment towards customer focus to demonstrate that: <ul style="list-style-type: none"> ○ External requirements are determined understood and met e.g. contracts, legislation, benchmarking, surveys, customer satisfaction, market intelligence, future trends, customer expectations ○ Risks and opportunities (see 6.1) e.g. competition, capability, resourcing, barriers to market, investment, business continuity, innovation, future trends, new technology, new products/services, building on current strengths are determined and addressed ○ Focus on enhancing customer satisfaction (see 9.1.2) is maintained e.g. building relationships, conducting surveys, customer feedback, customer communication, customer performance, complaint profile, evaluation of repeat business and identifying opportunities for strengthening the organization reputation and market presence ○ Customer perception (determined by the customer) and customer satisfaction (measured by the organization) are aligned ○ Product and service conformity and on-time delivery performance is measured e.g. defining performance criteria, flow down across the organization, setting targets, data capture, data reporting, management review ○ Action is taken when product and service conformity and on-time delivery performance is not achieved e.g. ownership, containment, root cause, corrective action, continual improvement

5.2	Policy
5.2.1	<p>Establishing the Quality Policy Things to consider:</p> <ul style="list-style-type: none"> • Top management provision for establishing the quality policy including: <ul style="list-style-type: none"> ○ Appropriateness and alignment to the context of the organization (see 4.1), e.g. purpose, strategic direction, mission, vision, ethical principles, business reputation, core values, business/functional policies, codes of conduct etc. ○ Establishment of a framework for setting quality objectives (see 6.2), e.g. business planning, core themes, strategic enablers, key performance indicators (KPIs), milestones, resources ○ Commitment to satisfy applicable internal/external requirements e.g. industry, business, customer, statutory, regulatory and other interested parties (see 4.2) ○ Commitment towards continuous improvement of the QMS e.g. business performance, process maturity, process effectiveness, customer expectations, investment, organizational growth, scope application • Top management provision for implementing and maintaining the quality policy (see 5.2.2)
5.2.2	<p>Communicating the Quality Policy Things to consider:</p> <ul style="list-style-type: none"> • Arrangements for communicating the quality policy within and outside of the organization including: <ul style="list-style-type: none"> ○ Availability across the organization and methods used to deploy e.g. hard copies displayed in prominent places, electronic copies via intranet/internet sites, identification and distribution to relevant interested parties ○ Awareness, understanding and application across the organization (see 7.3 and 7.4) e.g. communication methods (meetings, briefs, e-mail, websites), responding to feedback, providing interpretation, translation into other languages (as required), timing and frequency • Maintaining documented information to demonstrate that the quality policy is controlled, reviewed periodically for continuing suitability, updated as required and subject to further communication accordingly e.g. ownership, review, validity, applicability, distribution, feedback

5.3	<p>Organizational Roles, Responsibilities, and Authorities</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Top management provision for assigning relevant roles and responsibilities (i.e. tasks allocated to a role) and authorities (i.e. permissions allocated within the role). • Assignment of relevant roles, responsibilities and authorities across the organization e.g. top management, management representative, functional leaders, heads of departments, process owners, lead process users, end users etc. relating to: <ul style="list-style-type: none"> ○ Conformance of the QMS to the 9100 standard (see 4.3) ○ Delivery of process output results (see 4.4.1) ○ Reporting of QMS performance and improvement opportunities (see 9.3) ○ Promoting customer focus (see 5.1.2) ○ Maintaining the integrity of the QMS when changes occur (see 6.3) • Arrangements to demonstrate that relevant roles, responsibilities and authorities are communicated and understood, e.g. organization chart, resource allocation, role profiles, accountability statements, job descriptions, terms of reference, training, competence, qualification, performance review • Appointment of a specific management representative who has: <ul style="list-style-type: none"> ○ Responsibility and authority for oversight of the above e.g. assignment of specific duties, defined responsibilities, clear accountabilities ○ Organizational freedom and unrestricted access to top management to resolve quality management issues, including liaison with external parties (as appropriate) e.g. organizational structure, hierarchy, reporting lines, conflicts of interest, independence, recognized authority
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Clause #	Considerations
6.	PLANNING
6.1	Actions to Address Risks and Opportunities
6.1.1	<p>Things to consider:</p> <ul style="list-style-type: none"> • Organization determination of the risks and opportunities when planning for the QMS arising from: <ul style="list-style-type: none"> ○ External and internal issues (see 4.1) ○ Requirements of relevant interested parties (see 4.2) • Organization arrangements for addressing the identified risks and opportunities, including those that have an impact on: <ul style="list-style-type: none"> ○ The QMS achieving its intended results e.g. conformity to requirements, realizing objectives, meeting performance targets ○ Enhancing the desirable effects e.g. developing opportunities, creating new possibilities, exploring new markets, expanding the customer base, organization growth ○ Preventing or reducing undesired effects e.g. proactive risk management, focusing on risk reduction, taking preventive measures ○ Achieving improvement e.g. meeting targets, removing non-value added activity (waste), positive performance trends
6.1.2	<p>Things to consider:</p> <ul style="list-style-type: none"> • Organization arrangements for: <ul style="list-style-type: none"> ○ Planning actions to address the identified risks and opportunities to ensure that appropriate process controls are in place e.g. ownership, documented information, instructions, methods, verification activity, process monitoring, performance measures and trends, training, competency ○ Integrating and implementing actions into the QMS e.g. capture of lessons learned, sharing good practice, process reviews, process updates, change control, communication ○ Evaluating the effectiveness of the actions taken including; management review, effect on product and service conformity, achieving planned activities and planned results, monitoring of trends, effect on customer satisfaction etc. • Organization approach to managing risks and opportunities taking into account: <ul style="list-style-type: none"> ○ Level of activity proportionate to the size and complexity of the organization and the impact on the conformity of products and services ○ Application of risk management techniques including; risk management plan, risk identification, likelihood/impact of occurrence, severity of outcome (e.g. high, medium, low), risk ownership, risk treatment, residual risk, continual monitoring

	<p>etc.</p> <ul style="list-style-type: none"> ○ Taking advantage of new opportunities by building on current strengths, anticipating future trends, introducing new technology, developing new products or services, opening new markets, attracting new customers etc. <p>NOTE: There are many tools and methodologies that an organization can adopt to help manage risks and identify opportunities including; learning from the past (Lessons Learned), PEST (Political, Economic, Social, Technological), PESTLE (Political, Economic, Social, Technological, Legal, Environmental) SWOT (Strengths, Weaknesses, Opportunities, Threats), FMEA (Failure Modes and Effects Analysis, brainstorming techniques, BCM (Business Continuity Management), benchmarking etc.</p>
6.2	Quality Objectives and Planning to Achieve Them
6.2.1	<p>Things to consider:</p> <ul style="list-style-type: none"> • Organization arrangements for setting quality objectives at various levels across the organization including: <ul style="list-style-type: none"> ○ Objectives established within the relevant functions (Engineering, Purchasing, Finance, Human Resources, Quality, IT etc.), linked to the respective functional strategy, e.g. functional direction, process improvement, milestones etc. ○ Objectives established within relevant processes that could include; direction defined by the process owner relating to the aims of the process, e.g. what the process is trying to achieve, resources needed, timescales etc. ○ Objectives established and suitably cascaded at various levels across the organization structure e.g. top management, middle management, supervisors, departments, projects, groups, individuals • Maintaining documented information to demonstrate that the quality objectives are: <ul style="list-style-type: none"> ○ Consistent with the quality policy (see 5.2.1) to ensure that they underpin the strategic direction of the organization, support the needs and expectations of interested parties and enhance customer satisfaction ○ Specific and measurable in order to give clear direction as to what is required and the expected outcome, often referred to as SMART (Specific, Measurable, Attainable, Realistic and Time-bound) objectives ○ Aligned to applicable requirements e.g. those defined by the organization, customer or regulator and relevant to the conformity of products and services ○ Monitored using suitable means to ensure that the objectives are being met e.g. Business Plan Deployment (BPD) charts, dash boards, matrices, reports, progress charts, traffic light charts, management review ○ Communicated at the relevant levels within the organization to ensure that teams and individuals are aware of their importance and contribution ○ Updated accordingly to demonstrate progress and to take account of changing circumstances that could result in new,

	expanded, amended, cancelled objectives etc.
6.2.2	<p>Things to consider:</p> <ul style="list-style-type: none"> • Organization planning to achieve its established quality objectives including the determination of: <ul style="list-style-type: none"> ○ What will be done e.g. clearly established objectives across the organization at various levels (functional, process, department, team, individual) that are measurable - see 6.2.1. ○ Resources required to deliver the objectives e.g. number and competency of people, adequate infrastructure, suitable working environment, organizational knowledge, investment, budgets, external provision ○ Responsibility for achieving objectives at the various levels within the organization e.g. top management, functional leadership, department leadership, process owners, teams, individuals ○ Timescales for achieving objectives e.g. stepped achievement (weekly, monthly, quarterly), specific milestones (defined dates or periods), annual achievement ○ Methods used to evaluate the results e.g. periodic comparison of performance against established targets or expectations during management review, functional reviews, process councils, departmental reviews, personal development reviews (appraisals), team meetings
6.3	<p>Planning of Changes</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • The approach taken by the organization to ensure that changes to the QMS are planned and implemented in a controlled manner taking into account: <ul style="list-style-type: none"> ○ The reason for the change; e.g. context of the organization (see 4.1), needs of interested parties (see 4.2), customer feedback, complaints analysis, audit results, performance trends, risk reduction or realizing an opportunity (see 6.1), continual improvement, organization growth, launch of new products/services, organization restructuring etc. ○ Assessing the purpose of the change(s) and potential impact using a risk based thinking approach to ensure the integrity of the QMS is maintained i.e. focus on priorities, avoid disruption, ensure business continuity, maintain product/service reliability, protect the customer, maintain capability, continue to meet internal/external requirements etc. ○ The resources required to enable the change such as people, knowledge acquisition, infrastructure, environment, budget, trials/tests, ongoing monitoring, structured reviews etc. ○ Determination of responsibility and authority for the change e.g. process owner, lead process users, end users etc., including the necessary communication, training and ongoing review to ensure the change is effective (i.e. the planned activities continue to be realized and planned results are being achieved)

Clause #	Considerations
7.	SUPPORT
7.1	Resources
7.1.1	<p>General Things to consider:</p> <ul style="list-style-type: none"> • Organization determination of the resources needed for the establishment, implementation, and continual improvement of the QMS taking into account: <ul style="list-style-type: none"> ○ Resource planning, including load/capacity balance, make versus buy analysis ○ Utilization of existing internal resources e.g. people, facilities, materials, equipment, finance, capability, capacity, information ○ Utilization of resources provided by external providers e.g. processes, products, services
7.1.2	<p>People Things to consider:</p> <ul style="list-style-type: none"> • Organization approach for providing the necessary people to ensure effective implementation and control of the QMS e.g. organizational knowledge, capability, skill set, competency, experience, workforce agility, recruitment (temporary, permanent), terms of employment
7.1.3	<p>Infrastructure Things to consider:</p> <ul style="list-style-type: none"> • Determination of the required infrastructure to enable the strategic and operational needs of the organization including: <ul style="list-style-type: none"> ○ Buildings e.g. manufacturing/assembly plants, test facilities, laboratories, service centers, offices ○ Utilities e.g. electricity, gas, water, compressed air ○ Equipment e.g. machine tools, jigs, fixtures, tooling, work stations, IT equipment, software programs, asset care ○ Transportation e.g. materials/equipment handling (internal/external), packaging/protection, hazardous substances ○ Information and communication technology e.g. IT infrastructure (servers, back up systems, business continuity, accessibility, security, networks) • Consideration of facilities management e.g. organizational footprint, real estate planning, sustainability (energy usage, emissions), statutory inspections, restricted areas, hard services (infrastructure maintenance and disposal), soft services (cleaning, catering, security)

7.1.4	<p>Environment for the Operation of Processes</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Determination of the required environment to enable the strategic and operational needs of the organization including: <ul style="list-style-type: none"> ○ Social environment e.g. ethics, equality, diversity, behaviors, policies, codes of conduct, ○ Psychological environment e.g. workload, working hours, time constraints, conflicting demands, flexible working, health and well being, confidential reporting lines ○ Physical environment e.g. space, ergonomics, workplace organization (5S), visual management (layout, zoning, signing etc.) cleanliness, restricted areas, electrostatic discharge, lighting, temperature, humidity, ventilation, noise, FOD prevention, waste reduction (Lean)
7.1.5	Monitoring and Measuring Resources
7.1.5.1	<p>General</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Determination of the resources required to enable valid and reliable results when monitoring (checking, inspecting observing or witnessing activity) and measurement (determination of physical characteristics) is applied to verify or validate process, activity, product and service conformity • Monitoring and measuring can vary depending upon the complexity and needs of the organization, requirements of the output and expectations of the customer • The selection and application of appropriate resources after considering the characteristics, features and attributes of the activities being undertaken • Monitoring and measurement resources can include suitable people, facilities, instruments, gages, equipment, devices etc., that are both internal or external to the organization • Maintenance of the monitoring and measurement resources to ensure continued adequacy including for example: <ul style="list-style-type: none"> ○ People training and competency provision ○ Facility maintenance regimes ○ Asset care programs ○ Calibration arrangements • Documented information to demonstrate that the resources utilised continue to be appropriate and adequate including for example: plans, schedules, databases, systems, registers, certificates, traceability to recognized standards (where required)

7.1.5.2	<p>Measurement Traceability</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization approach in understanding and applying the necessary arrangements in order to validate measurement results for example: <ul style="list-style-type: none"> ○ Identification and location of measurement equipment (organization, personal, customer owned) ○ Identification of calibration equipment (gage number, serial number, reference number) ○ Methods of calibration (procedures, instructions, guides) ○ Measurement standards and acceptance criteria (organization, national, international) ○ Frequency of calibration and recall (time period, advance notice, due dates, overdue notices) ○ Suitable environmental conditions (cleanliness, temperature, humidity) ○ Calibration status (marking, tagging, labeling, color coding) ○ Protection and preservation (storage conditions, prevention of adjustment, protection from damage) ○ Measurement capability (interval analysis, gage Repeatability & Reproducibility (R&R), measurement uncertainty, measurement system analysis) • Arrangments for maintaining documented information including for example: <ul style="list-style-type: none"> ○ Equipment register (type, identification, location, method, frequency, acceptance criteria) ○ Records of calibration (identity, description, date, condition, results, authority, interval, next due date, adjustments, limitations of use) • Action taken when measuring equipment is found to be unfit for its intended purpose and its impact on previous measurement results (error reports, investigation, previous equipment useage, risk assessment, reporting, product recall)
7.1.6	<p>Organizational Knowledge</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organizational approach towards the determination and capture of knowledge including for example: <ul style="list-style-type: none"> ○ Planning for knowledge capture (knowledge management plan, present and future needs, sustainability, knowledge sources, approach, scope, ownership, timeliness, knowledge distribution) ○ Knowledge gained from experience (personal development, succession planning, subject matter expertise, mentoring programs, coaching, peer reviews, organization insight, business exposure) ○ Knowledge acquisition (intellectual property, patents, lessons learned over time, explicit and tacit knowledge, professional membership, industry associations, benchmarking, conferences, communities of practice, interested parties, journals,

	<p>academia)</p> <ul style="list-style-type: none"> • Maintain and share organizational knowledge (knowledge management system, electronic media, intranet, database, repository, libraries, communities of practice, new comer mentoring, subject matter experts, master classes, continual improvement, sharing good practice, QMS updates)
7.2	<p>Competence</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organisation determination of competency relating to person(s) and role(s) such as: <ul style="list-style-type: none"> ○ Defined competency requirements, including any specified induction, training, assessment, evaluation and qualification, role profiles, job descriptions, accountability statements, skills matrices, competency packs, performance criteria, development frameworks ○ Understanding resource needs and related competency (training needs analysis, gap analysis) ○ Provisioning the necessary competency through reassignment or development of existing person(s), or acquiring competent resource externally ○ Evidence of ability based on education, training, skills, knowledge, experience, professional membership etc. ○ Periodic assessment and evaluation of competency to ensure continued adequacy and effectiveness • Evidence of competency, including for example; training certificates, records of achievement, qualification statements, Individual Development Plans (IDP), Continued Professional Development (CPD), Body of Knowledge (BoK), On the job training (OtJ), log books, workplace assessments
7.3	<p>Awareness</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Demonstration of person(s) awareness of: <ul style="list-style-type: none"> ○ The quality policy (see 5.2) and relevant quality objectives (see 6.2) through effective two way communication e.g. prominence, briefings, visual display, intranet, newsletters, employee engagement, access and availability ○ Their contribution to the effectiveness of the QMS, and the benefits of improved performance e.g. Business Plan Deployment (BPD), flow down of objectives, appraisals, performance ratings, Quality/Cost/Delivery (QCD) performance monitors ○ Relevant documented information (including changes), their contribution to product/service conformity and the implication of not conforming with requirements e.g. access to the QMS, navigation of requirements, notification of changes, 'what's new' notices, nonconformance reporting, understanding of culpability and consequences ○ Their contribution to product safety e.g. individual accountabilities, compliance to process, attention to detail, safety

	<p>awareness training including product end usage and potential impact relating to product issues, notice boards, safety alerts, posters</p> <ul style="list-style-type: none"> ○ The importance of ethical behavior e.g. code of conduct, internal management/employee working relationships, fair treatment, employee work recognition, confidential reporting mechanisms, protecting anonymity, no blame culture, awareness campaigns, notice boards, posters, training programs
7.4	<p>Communication</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Use of a communication strategy, policy, plan • Organisation approach towards internal and external communication taking into account: <ul style="list-style-type: none"> ○ What is to be communicated e.g. policy, objectives, QMS requirements, processes, organization performance, customer satisfaction, changes etc. ○ When to communicate e.g. frequency, importance, significance, scheduled, adhoc, shift coverage ○ Who to communicate with e.g. relevant interested parties: <ul style="list-style-type: none"> ▪ External (customers, regulators, stakeholders, agencies, local community, investors, external providers, media) ▪ Internal (employees, employee representatives, contractors) ○ How communication occurs e.g. meetings, briefings, notices, e-mails, telephone, text, intranet, internet, directives, visual management, campaigns, social media, alerts, bulletins, WebEx's, webinars, press release, news letters ○ Who undertakes the communication: managers, supervisors, team leaders, team members, employee representatives, corporate communication, public relations, marketing, external providers • Methods to enable 'two way' communication as appropriate in order to verify understanding and capture feedback
7.5	<p>Documented Information</p>
7.5.1	<p>General</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Arrangements for ensuring that the QMS includes documented information appropriate to the organization (size, products, services, processes, complexity, competency etc.) required by: <ul style="list-style-type: none"> ○ 9100 standard ○ Organizations own requirements

7.5.2	<p>Creating and Updating</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Arrangements for creating and updating documented information including: <ul style="list-style-type: none"> ○ Identification and description e.g. subject title, document identification, date, author, reference number, version number, change history, retention category, retention period, security classification, export control, intellectual property classification, copyright ○ Format e.g. language, software version, layout, pagination, style, fonts, resolution, hyperlinks and media e.g. paper, magnetic, electronic or optical computer disc, photograph, master sample, IT system, portable media, microfiche, X-ray film ○ Review and approval e.g. review periods, permissions, authorized persons, review methods (interested parties, draft release, ballot, buy off, final release)
7.5.3	Control of Documented Information
7.5.3.1	<p>Things to consider:</p> <ul style="list-style-type: none"> • Arrangements for controlling documented information required by: <ul style="list-style-type: none"> ○ 9100 standard ○ Organizations own requirements • Availability e.g. document accessibility (hard copy, electronic media), readily available at the point of use • Suitability e.g. format, media suitable to the environment, ease of understanding, language, interpretation • Protection e.g. document authentication, document markings (official, secret, restricted, confidential, private, sensitive, classified, unclassified), access controls (individual, role specific), physical security (master documents, server rooms, libraries) IT security (User ID, password, servers, download, back up, encryption, 'read only', 'read/write'), protection from corruption and unintended alterations
7.5.3.2	<p>Things to consider:</p> <ul style="list-style-type: none"> • Document control arrangements including: <ul style="list-style-type: none"> ○ Distribution (internal/external) e.g. infrastructure, networks, portals, document registers, points of contact, transmission ○ Access and retrieval e.g. location, availability, timeliness, remote access ○ Storage and preservation e.g. physical environment, protection from fire and flood, filing arrangements, physical/IT security, sustainability, redundant hardware/software to access legacy media, archive arrangements ○ Change control e.g. document review, change notices, version control, change history, re-issue, communication, distribution ○ Retention e.g. organization/legal/contractual retention periods, storage, preservation, back up, retention of knowledge, disposal

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| | <ul style="list-style-type: none">○ Obsolescence e.g. withdrawal, replacement, legacy archive and suitable identification (“for information only”, “not to be used after...”, “uncontrolled copy”, “for reference purposes only” etc.○ Electronic data protection e.g. security policy, system access profiles, password rules, storage and back-up policy including protection from loss, unauthorized changes, unintended alteration, corruption, physical damage• Identification and control of external documented information e.g. ownership, customer property, whereabouts, accessibility, points of contact, change notices, distribution, return, disposal, document markings, licensing, copyright, links to external repositories |
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Clause #	Considerations
8.	OPERATION
8.1	<p>Operation Planning and Control</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization approach, including relevant function engagement (e.g. planning, engineering, operations, purchasing, quality) to plan, implement and control operational activity, taking into account: <ul style="list-style-type: none"> ○ Actions arising from organization risks and opportunities, quality objectives and changes to the QMS (see clause 6) ○ Provision for determining requirements relating to the organization and interested parties (see 8.2.2) ○ Establishment of process criteria e.g. inputs, outputs, controls, resources, sequence, interaction, measures, responsibilities (see 4.4) ○ Establishment of criteria for acceptance of products and services e.g. measurement, monitoring, inspection, verification, validation, test, statistical techniques ○ Determination of internal/external resources to ensure conformity and on-time delivery e.g. people, facilities, materials, equipment, finance, information, outsourced processes, products and services, including the use of systems such as Enterprise Resource Planning (ERP), Material Planning System (MPS), Material Resource Planning (MRP), load/capacity models, sales order review, forecasting techniques, process simulation ○ Control of the processes in accordance with criteria to demonstrate that intended outputs are met and improvements identified e.g. process achievement, expected outcome, opportunities for improvement ○ Other methods determined by the organization such as an integrated phased process approach e.g. Advanced Product Quality Planning (APQP), Production Part Approval Process (PPAP) • Determination and retention of documented information to ensure process control e.g. operational process definition, production planning and control, operational instructions, production system, product data management, quality plans • Determination and retention of documented information to demonstrate conformity e.g. process output records, verification/validation results, schedule adherence, performance measures, management review output • Determination of the processes and controls needed to: <ul style="list-style-type: none"> ○ Manage critical items (items that have a significant effect on the provision and use of the products and services – see 9100 3.2) e.g. parts classification, critical part plans, source and method change, traceability, service life management ○ Manage key characteristics (an attribute or feature whose variation has a significant effect on product fit, form, function,

	<p>performance, service life, or producibility – see 9100 3.3) e.g. component proving, process control plan, measurement and evaluation techniques, review and disposition</p> <ul style="list-style-type: none"> • Determination of the process and resources needed to manage use and maintenance of the product or service e.g. service network, technical services, technical publications, problem resolution system, feedback mechanisms, product support, aftermarket support • Determination and control of the products and services to be obtained from external providers e.g. resource planning, load/capacity balance, make versus buy analysis, outsourcing policy, outsourcing processes, source change (including permanent or temporary work transfer to an external provider, or from one external provider to another) • Establishment of controls needed to prevent delivery of nonconforming products and services e.g. process control, verification/validation activity, component proving, risk management, customer eyes, delegated product release verification • Appropriate planning and management of product and service provision e.g. project planning, project management, program management taking into account: project management plans, quality plans, work breakdown structure, sequencing, phases, deliverables, dependencies, constraints, risks, resources, achievement of milestones • Control of planned and unintended changes (e.g. to requirements, processes, sources, methods, schedule, volumes) and considering communication, impact and mitigation of risks, pre-post change evaluation etc.
8.1.1	<p>Operational Risk Management Things to consider:</p> <ul style="list-style-type: none"> • Organization arrangements for managing risk within operations (planning and control, project management, requirements for products and services, design and development, external provision, production and service provision), taking into account: <ul style="list-style-type: none"> ○ Assignment of responsibilities e.g. risk owners, facilitators, champions, coordinators, managers, action owners ○ Risk criteria e.g. criteria relating to the magnitude of risk, probability/likelihood (very high, high, medium, low, very low), impact/consequence (critical, significant, marginal, negligible) ○ Risk activity: <ul style="list-style-type: none"> ▪ Identification e.g. scope, risk identity, “if/then” statements, reference numbers ▪ Assessment e.g. risk treatment, risk analysis, application of criteria, risk levels, scoring, ranking, prioritization, key risks, risk assessment matrix, risk register ▪ Communication e.g. stakeholder engagement, monitoring and measurement, risk aggregation, risk status, risk transfer, risk reports, risk management systems ▪ Management of actions e.g. planning, identity, ownership, timescales, review, risk analysis update ▪ Risk acceptance e.g. residual risk, As Low As Reasonably Practical (ALARP), rational risk, proceed at risk, contingency

	plans, read across of risk outcomes to other similar projects, activities, situations
8.1.2	<p>Configuration Management</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization approach to the management of configuration, taking into account: <ul style="list-style-type: none"> ○ Product identity and traceability e.g. Bill of Material (BoM), General Arrangement (GA), product breakdown structure, illustrated parts catalog, part numbering, part lists, ‘as produced’ condition, configuration (IT) system, standard parts (catalog, off the shelf), product log book, Product Lifecycle Management (PLM), Product Data Management (PDM) ○ Identified changes e.g. alteration requests, notice of change, amendments, deviations, waivers, part revision changes, part number changes, change categories, service bulletins, modification bulletins, airworthiness directives, engineering communication notices ○ Documented information is consistent with product/service attributes e.g. regulations, definitions, drawings, specifications, standards, models, component proving, production instructions and records (manufacturing, assembly, test, repair), product change records, authorization of change, type certificates
8.1.3	<p>Product Safety</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Arrangements for planning, implementing and controlling the processes needed to ensure product safety (ability for a product to perform to its intended purpose without causing unacceptable risk of harm to persons or damage to property – see 9100 3.4) including for example: <ul style="list-style-type: none"> ○ Assessments of hazards and management of risk e.g. risk assessment, Design Failure Modes and Effects Analysis (DFMEA), Process Failure Modes and Effects Analysis (PFMEA), safety analysis, Failure Modes Effects and Criticality Analyses (FMECA), fault tree analysis ○ Management of Safety critical items e.g. monitoring control plan, critical part plans, inspection and service intervals, component lifing, cyclic life, life management plans ○ Analysis, reporting and communication of occurred events e.g. data collection and analysis, internal escalation process, mandatory reporting, safety alert reports, in-service reliability, operating performance and trends, lessons learned, shared industry experience, product safety reviews, airworthiness directives ○ Training and communication e.g. product safety policy, promoting a safety culture, product integrity training, product safety training, awareness campaigns, safety notices, safety alerts, individual reporting mechanisms

8.1.4	<p>Prevention of Counterfeit Parts</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Arrangements for planning, implementing and controlling the processes needed to prevent counterfeit of suspect counterfeit parts (unauthorized copy, imitation, substitute or modified part which is knowingly misrepresented – see 9100 3.1) including for example: <ul style="list-style-type: none"> ○ Planning e.g. policy, counterfeit parts plan, governance arrangements, risk assessment, detection strategies, counterfeit sources, reporting, training, engagement with external providers, communication ○ Functional training (prevention, mitigation, detection, disposition and reporting): ○ Procurement e.g. trusted source selection ○ Inspection e.g. prevention of counterfeit items (visual/test) ○ Engineering e.g. Obsolescence management ○ Awareness e.g. campaigns, posters, alerts ○ Obsolescence monitoring e.g. design decisions and part selection appropriate for service life of product ○ Part acquisition e.g. Original Equipment Manufacturers (OEM), authorized distributors, other approved sources ○ Assuring traceability to OEM, authorized manufacturer, approved external provider ○ Verification and test methodologies e.g. part markings, visual features, inspection of attributes, functional test and validation, packaging ○ Preventing re-entry into the supply chain (see 8.7.1) e.g. labeling, marking, segregation, quarantine, containment, disposition, lessons learned, annotation of documented information, electronic system (MRP) updates ○ Reporting e.g. occurrences, events, external intelligence gathering (databases, notifications, reporting), read across to other products/services, escalation, risks to interested parties, external communication
8.2	Requirements for Products and Services
8.2.1	<p>Customer Communication</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization approach towards communicating with the customer in relation to: <ul style="list-style-type: none"> ○ Product/service information e.g. promotional material, telephone, journals, conferences, seminars, exhibitions, trade shows, catalogues, brochures, marketing campaigns, social media (websites, message boards) ○ Handling enquiries, contracts or orders e.g. engagement, support, points of contact, accessibility, help line, call centers, internet ‘contact us’, customer ledger ○ Handling changes to enquires, contracts or orders e.g. change notices, amendments, ledger updates

	<ul style="list-style-type: none"> ○ Collating customer feedback (see 9.1.2) e.g. satisfaction surveys, questionnaires, meetings, social media, forums, events, complaint profile, report cards ○ Handling customer property e.g. registers, identification, location, preservation, maintenance, storage ○ Contingency actions (if required) e.g. back up plans, alternative arrangements, proactive engagement, consideration of risk
8.2.2	<p>Determining the Requirements for Products and Services</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Determination of requirements including: <ul style="list-style-type: none"> ○ Defined requirements taking into account: <ul style="list-style-type: none"> ▪ Statutory and regulatory requirements e.g. Airworthiness regulations, ITAR/EAR, REACH, CS-25 international / national legislation, certification assurance (CE, UL etc.) ▪ Organization requirements e.g. product/service knowledge, understanding of customer stated and implied needs, lessons learned, derived requirements from previous projects, conceptual thinking, operational parameters (producibility, safety, reliability, obsolescence, disposal etc.) ▪ Special requirements e.g. requirements identified as high risk, such as product or process complexity, past experience (lessons learned), product/process maturity, boundaries of performance, technical or process capability, identification of critical items (see 9100 3.5) ○ Organization ability to meet requirements e.g. internal/external resources (people, facilities, materials, equipment, finance, information), capability, capacity, expertise, product/service validation, operational risk (new technology, short lead times, resource constraints, interdependencies)
8.2.3	Review of the Requirements for Products and Services
8.2.3.1	<p>Things to consider:</p> <ul style="list-style-type: none"> • Organization review of requirements coordinated with applicable functions (e.g. sales, planning, engineering, operations, purchasing, finance, legal, quality), before committing to supply products and services including: <ul style="list-style-type: none"> ○ Requirements specified by the customer e.g. within enquiries, contracts, purchase orders, statements of work, memos of understanding, letters of intent, terms and conditions ○ Requirements implied by the customer e.g. use of previous contract review activity, customer preferences, customer feedback, organization/industry knowledge, lessons learned, marketplace/competitor intelligence, in service performance data, previous experience, read across from other similar products or services ○ Requirements for delivery and post delivery e.g. logistics, shipping, transport, installation, commissioning, training, handover,

	<p>customer acceptance, warranties, repairs, customer support</p> <ul style="list-style-type: none"> ○ Organization (e.g. policies, processes, procedures, standards, specifications, rules, codes of practice) and, statutory/regulatory requirements (e.g. airworthiness regulations, ITAR/EAR, REACH, CS-25 international / national legislation, certification assurance (CE, UL etc.)) • Resolution of contract or order requirements that have been subject to change e.g. identification of the differences, communicating with the customer, clarification and understanding, impact assessment, mutually acceptable outcome • Confirmation of requirements when they are not documented e.g. clarification, understanding, acknowledgement and subsequent agreement in the form of retained documented information
8.2.3.2	<p>Things to consider:</p> <ul style="list-style-type: none"> • Retention of documented information to capture the results of the review including any new requirements or changes e.g. record of contract review, including for example customer, reference, date, persons, resources, conventional/special requirements, risks outcome, changes
8.2.4	<p>Changes to Requirements for Products and Services</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Amended documented information and communication of changed requirements e.g. updated contract review records, amended orders/contracts, memos, change notices, quality plans, meeting minutes, together with communication to relevant interested parties (persons within or outside the organization that may be impacted by the change)
8.3	Design and Development of Products and Services
8.3.1	<p>General</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization arrangements for establishing, implementing and maintaining a design and development process including planning, inputs, controls, outputs and changes (see 8.3.2 to 8.3.6)
8.3.2	<p>Design and Development Planning</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization approach towards planning design activity including: <ul style="list-style-type: none"> ○ Scope of the design e.g. requirements capture (see 8.2.2) rationale, assumptions, objectives, complexity, size, detail, timescales, criticality, constraints, risks, producibility, maintainability ○ Stages of the design process, distinct activities and review e.g. work breakdown structure, work packages (tasks, resources, responsibilities, content, inputs/outputs), concept design, preliminary design, detail design, review gates (preliminary design

	<p>review, detail design review, critical design review)</p> <ul style="list-style-type: none"> ○ Verification and validation activity e.g. checks, trials, tests, simulations, demonstrations required to ensure requirements are met ○ Responsibilities and authorities e.g. role profiles, accountability statements, delegation of authority, levels of approval, register of authority and approvals, authorized signatories ○ Internal/external resources e.g. knowledge acquisition, people, competency, investment, funding, facilities, equipment, innovation, technology, interested parties (customers, external providers, research establishments), information (principles, standards, rules, codes) ○ Organizational interfaces (persons/functions) e.g. sales, project management, production, procurement, quality, finance, customers, end users ○ Subsequent provision and application e.g. forward thinking, read across, re-use of new technologies, product/service derivatives, sustainability, recognizing obsolescence ○ Levels of control required or implied by interested parties (customers, regulators, end users etc.) e.g. customer acceptance, safety checks, risk management, verification/validation activity, product certification ○ Required documented information e.g. design plan, design reviews, design outputs (specifications, schemes, drawings, models, data, reports), control plans, certificates
8.3.3	<p>Design and Development Inputs</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Determination of input requirements together with the retention of documented information including: <ul style="list-style-type: none"> ○ Functional and performance requirements e.g. customer needs, operating characteristics, performance parameters, safety, usability, reliability, maintainability ○ Information transfer e.g. read across from other similar designs, lessons learned, performance data, in-service data, customer feedback, external provider feedback, best practice, benchmarking ○ Statutory and regulatory requirements e.g. legislation, regulations, directives ○ Standards or codes of practice e.g. policies, standards, specifications, rules and aids, protocols, guidance, industry codes ○ Consequences of failure e.g. risk profile, DFMEA, safety analysis, FMECA, fault tree analysis, lessons learned ○ Consequence of obsolescence e.g. source of supply, sustainability, prohibited materials and substances, conflict minerals, speciality materials, proprietary parts, exposure of counterfeit ○ Adequacy of inputs e.g. clear, complete, unambiguous, understandable, transmittable ○ Conflicting inputs are resolved e.g. functional consensus, communicating with interested parties, contract/order amendment,

	interested party agreement, mutually acceptable outcome
8.3.4	<p>Design and Development Controls</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Determination of controls together with the retention of documented information including: <ul style="list-style-type: none"> ○ Definition of outcomes e.g. design intent, functional and performance requirements, customer/end user expectations ○ Design review e.g. functional representation (customer, engineering, production, quality, project management etc.), review gates (preliminary design review, detail design review, critical design review), commercial/technical considerations, authorized progression to next stage (proceed to next gate) ○ Verification activity e.g. modeling, simulations, alternative calculations, comparison with other proven designs, experiments, tests, specialist overview (stress, performance etc.) ○ Validation activity e.g. functional testing, performance testing, trials, prototypes, demonstrations, simulations ○ Management of actions arising from design review, verification or validation e.g. action registers, ownership, timescales, escalation, changes to risk profile
8.3.4.1	<p>Things to consider:</p> <ul style="list-style-type: none"> • Planning and controlling verification and validation tests including: <ul style="list-style-type: none"> ○ Test requirements e.g. product identity, objectives, schedules, plans, specifications, resources (persons, equipment, infrastructure), parameters, conditions, acceptance criteria (pass, fail etc.) ○ Test methods e.g. instructions, procedures, schedule, checklists, log books, diaries, data capture ○ Configuration e.g. product configuration (item, assembly, module, product) and test configuration (facilities, equipment, conditions, software, controlled monitoring and measuring devices – see 7.1.5) ○ Retained documentation to demonstrate that the: <ul style="list-style-type: none"> ▪ Test plan and test procedures have been observed and criteria has been met ▪ Design meets the specified requirements for all identified operational conditions e.g. reports, calculations, test results, data, reviews, outputs
8.3.5	<p>Design and Development Outputs</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Outputs meet input requirements e.g. checklists, design review records, authorization to proceed, customer acceptance, product certification • Outputs are adequate for product and service provision e.g. standards, specifications, schemes, drawings, models, part lists, materials,

	<p>methods, manufacturing instructions, technical packages, tooling, machine programs, preservation, handling, packaging, specialist training, user instructions, service manuals, repair schemes, external provision, together with:</p> <ul style="list-style-type: none"> ○ Reference to monitoring and measuring equipment e.g. inspection equipment, gages, instruments, environment ○ Acceptance criteria e.g. product/service specification, limits, tolerances, quality acceptance standards ○ Product/service characteristics e.g. key characteristics, customer critical features, interface features, inspections, service intervals, operating characteristics, ○ Critical items (see 9100 3.2) e.g. identification, key characteristics, special handling, service intervals, component lifing, cyclic life, life management plans, source and method change, traceability <ul style="list-style-type: none"> • Outputs are approved prior to release e.g. scope of authorization, authorized persons, levels of authorization, method of authorization and documented information is retained
8.3.6	<p>Design and Development Changes</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization approach for the identification, review and control of changes including: <ul style="list-style-type: none"> ○ Implementation of a process to notify the customer when changes affect the customer requirement e.g. customer communication, notifications of change, requests for deviation, contract amendments ○ Configuration control e.g. alteration requests, notice of change, amendments, deviations, waivers, concessions, part revision changes, part number changes, change categories, service bulletins, modification bulletins, airworthiness directives, engineering communication notice, product change boards • Retained documented information that includes change history, evaluation of change results, authorization of change and actions taken in relation to subsequent activities that are impacted by the change
8.4	Control of Externally Provided Processes, Products and Services
8.4.1	<p>General</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization arrangements for ensuring external provided processes, product and services conform to requirements when: <ul style="list-style-type: none"> ○ Incorporated into the organizations own products and services e.g. bought out finished/complete products/services ○ Provided directly to the organizations customer e.g. direct ship, direct delivery ○ A process or part of a process is provided e.g. outsourcing, offload, operational processing (conventional/special processes etc.), support provided on-site at the organization premises (IT support, facilities management etc.)

- Taking into account:
 - Retaining responsibility for external provision from all sources, including those defined by the customer e.g. organization takes full responsibility, irrespective of any sources identified by the customer
 - The use of approved external providers including those designated by the customer e.g.
 - Sourcing from an approved supplier list where the organizations approval scope matches the requirements
 - Sourcing in accordance with customer instructions (communications, contracts, memoranda etc.)
 - The identification and management of risks (see 8.1.1) associated with:
 - External provision e.g. assignment of responsibilities, risk criteria, risk identification, risk assessment, communication, management of actions, risk acceptance
 - Selection and use of external providers considering such things as: structure (ownership, parent company, subsidiaries, location etc.), market intelligence, customer input, financial stability, capability, terms and conditions, ratings, approvals (customer, regulator, 3rd party etc.)
 - The application of appropriate controls to ensure that external providers control their direct and sub-tier external providers e.g. approvals, contract conditions, flow down requirements, purchase order terms, mandatory instructions, non disclosure agreements, statutory/regulatory directives, delegations
- Applying criteria for the evaluation, selection, monitoring and re-evaluation of external providers including:
 - Commodity strategy e.g. products, services, categories, interested party requirements
 - Sourcing strategy e.g. policies, scope, goals, objectives, requirements capture, risks
 - Selection criteria e.g. profile, portfolio, location, pre-requisites, capability, market intelligence, strategic alignment, financial stability, ethical performance, external approvals, externally available data and information (reports, disclosures, satisfaction indexes, performance ratings, reputation, other party feedback etc.),
 - Approval methodology e.g. approval requests (new, extended etc.), scope of approval, external approvals/certifications (customer, regulator, 3rd party etc.), authorized persons, 2nd party audit activity, approval status (approved, suspended, withdrawn, lapsed, conditional, disapproved etc.)
 - Performance monitoring e.g. measures, targets, KPIs, score cards, dash boards, ratings, surveys
 - Retained documented information and actions arising from the evaluations e.g. approved supplier list, audit reports, performance reports, risk assessment, requests for information (RFI), dispositioned approval requests, certificates, gap analysis, corrective action reports

8.4.1.1	<p>Things to consider:</p> <ul style="list-style-type: none"> • Defined process, responsibilities and authority for external provider approval, including for example supplier selection and approval process, roles and accountability statements, levels of authorization, scope of approval (products, services, processes, commodities etc.), changes to approval (approved, suspended, withdrawn, lapsed, conditonal, disapproved etc.), monitoring and measurement (performance reviews, surveillance activity etc.) • Maintained register of external providers including for example approved vendor list, approved supplier list, vendor database, scope statements, approval status • Periodic review of external provider performance including conformity, on-time delivery and other pertinent measures (KPIs, targets, measures, values), performance reviews, management review, dash boards, flight decks, reports etc., and arrangements for taking action when requirements are not met e.g. containment, correction, root cause, corrective action, effectiveness of resolution, change to approval status • Defined requirements for controlling documented information created by and/or retained by external providers including: <ul style="list-style-type: none"> ○ Communication e.g. contract conditions, flow down requirements, purchase order terms, mandatory instructions ○ Document types (maintained/retained) and control (storage, protection, retrieval, media, retention periods etc.)
8.4.2	<p>Type and Extent of Control</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization approach towards ensuring that externally provided processes, product and services do not impact upon the delivery of conforming product to the customer, taking into account: <ul style="list-style-type: none"> ○ Externally provided processes remain within the organizations QMS control e.g. documented information is aligned to ensure common inputs, outputs, controls, ownership, governance etc., between the organization requirements and those that are used to interface with the external provider ○ The definition of controls applied to an external provider and those applied to the resulting output e.g. defined external provider requirements and alignment with the controls applied to the subsequent output ○ Consideration of: <ul style="list-style-type: none"> ▪ The impact of external provision and the organizations ability to consistently meet customer, statutory and regulatory requirements e.g. those defined in contracts, legislation and regulations ▪ The effectiveness of the controls applied to the external provider e.g. requirements, selection and approval, verification activities, performance monitoring, corrective action, continual improvement ○ Determination of verification activities according to the risks identified by the organization, that can include:

	<ul style="list-style-type: none"> ▪ Review of documented information e.g. certificates of conformity, test reports, release certificates, regulatory certificates (EASA Form 1, FAA 8130 etc.), process control documents, production process verification activity (see 8.5.1.3) etc. ▪ Inspection and audit at the external providers premises e.g. source inspection, oversight, witness, sampling, 3rd party verification, 2nd party audits, surveillance activity, process monitoring, product audits ▪ Review of Production Part Approval Process (PPAP) data e.g. control plan, product/process characteristics, statistical process control, risk assessment, measurement system analysis, verification results, PPAP file etc.) ▪ Inspection/verification upon receipt e.g. activity undertaken by the organization to confirm that outputs meet stated requirements that can include, defined levels of receipt inspection, physical inspection of the products, confirmation of the service provided, sampling in accordance with a defined plan ▪ Review of delegation for product verification e.g. requirements, criteria, scope, register of delegations, levels of authority/approvals, authorized signatories, periodic monitoring by the organization (oversight, witness, requalification etc.) ▪ Customer verification at any level of the supply chain e.g. oversight, witnessing, inspection, documentation review, product audit, product acceptance testing ○ Inspection or periodic testing when there is a high risk of nonconformity, including counterfeit parts e.g. identification, detection strategies, communication, MRP indication/signal/alerts, inspection levels, verification and test methodologies (part markings, visual features, inspection of attributes, functional test/validation etc.) ○ Control of products released for production use pending completion of verification activity e.g. identification, communication, document annotation, traceability, authorization to proceed, electronic system (MRP) updates, tracking/recall arrangements ○ Utilization of test reports during verification to confirm product requirements have been met e.g. evaluation of test report data (performance values, material properties, chemical composition, product attributes, functional characteristics etc.) ○ Validation of test report accuracy when raw material has been identified as a significant operational risk e.g. proving that test report data meets product requirements by conducting sample validation activity such as functional testing, performance testing, destructive testing, laboratory analysis of test specimens etc.
8.4.3	<p>Information for External Providers</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization arrangements to ensure the adequacy of requirements prior to communicating with the external provider e.g. clarity of requirements, clear understanding, unambiguous definition, identification of potential issues • Organization communication to the external provider including:

- Requirements of the processes, products and services that are being provisioned (identity, description, part numbers, quantity, delivery schedule, service parameters etc.), together with the identification of any technical data (standards, specifications, drawings, process requirements, instructions etc.)
- Approval of products, services, methods, processes, equipment and release e.g. criteria, requirements, acceptance, buy off, delegations, permissions, authorizations, licenses, conditions
- Competency requirements and person qualification e.g. skills, training, assessment, evaluation, levels of qualification, periodic re-assessment, maintained competence
- Interactions e.g. engagement, communication, reviews, meetings, exchange of documented information, notices, directives, feedback
- Control and monitoring of performance e.g. data capture, measures, targets, KPIs, score cards, dashboards, ratings, surveys
- Verification or validation activities at the external provider premises (including the customer) e.g. intent for source inspection, oversight, witness, sampling, 3rd party verification, 2nd party audits, surveillance, process monitoring, product audits, functional testing, performance testing etc.
- Control of design and development (see 8.3) e.g. requirements, statement of work, planning, controls (review, verification, validation etc.), delegations, maintained/retained documented information, design and development changes
- Special requirements, critical items, key characteristics e.g. specifications, performance criteria, risk management, identification, traceability, enhanced production/process controls, monitoring and measurement arrangements, fixed process approvals, product qualification, change control
- Test, inspection and verification e.g. requirements, instructions, acceptance criteria, equipment, production process verification (see 8.5.1.3), retained documented information
- Use of statistical techniques for product acceptance, including acceptance of instructions e.g. application of; statistical process control (SPC), process monitoring, sampling activity and organization acceptance of external provider arrangements (review, approval, buy off etc.)
- The need to:
 - Implement a QMS e.g. statement of requirements that can include alignment of the external providers QMS to recognized external standard (s), requirement to maintain relevant approvals/certification etc.
 - Use customer designated, or approved external providers e.g. statement of requirements relating to external provision of processes (including special processes), products and services from approved suppliers, including those flowed down by the organizations customer where applicable

	<ul style="list-style-type: none"> ▪ Notify nonconforming processes, products and services and obtain approval for their disposition e.g. statement of requirements relating the control of nonconforming outputs that can include process requirements, control arrangements, required documented information, reporting method, responsibilities and authorities (including delegation if applicable), implementing disposition instructions, nonconformity marking (e.g. concession numbers if applicable) etc. ▪ Prevent the use of counterfeit parts (see 8.1.4) e.g. statement of requirements that can include the need to conduct a risk assessment, use of approved external providers, verification and test methodologies, preventing re-entry into the supply chain (detection, segregation, quarantine, containment, disposition etc.), reporting occurrences, managing obsolescence etc. ▪ Notify changes to processes, products, services, including change of source/location e.g. statement relating to what constitutes a change (including changes to source and method) and the requirements for control, reporting, obtaining approval, acting upon the organizations response and maintaining process/product/service configuration as applicable ▪ Flow down requirements e.g. specific requirements required by the organization, or the organization's customer (as required) such as maintaining approvals, use of approved external sub-tier providers, verification requirements, notification requirements, reporting requirements etc. ▪ Provide test specimens for design approval, inspection/verification, investigation or auditing e.g. statement of requirement for the provision of test specimens/pieces/artifacts, including type, identification, configuration, supporting documented information, release conditions ▪ Retain documented information, including retention periods and disposition requirements e.g. statement of requirements relating to the control of records that can include type, media, back up, archive, storage, protection, preservation, access, retrieval, retention periods, disposal, return to the organization, security, data protection (electronic documented information) etc. ○ Right of access e.g. acceptance of the organizations right of access to the external providers premises to attend meetings, conduct performance reviews, review work in progress, conduct investigations, resolve problems, conduct 2nd party audits, support improvement activity, delivery of training ○ Ensuring persons are aware of: <ul style="list-style-type: none"> ▪ Their contribution to product/service conformity e.g. individual accountability, understanding requirements, compliance to process, the need to control changes, reporting of nonconformance ▪ Their contribution to product safety e.g. individual accountability, compliance to process, attention to detail, knowledge
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	<p>of product end usage, potential impact relating to product issues</p> <ul style="list-style-type: none"> ▪ The importance of ethical behavior e.g. code of conduct, management/employee working relationships, fair treatment, employee work recognition, confidential reporting mechanisms, protecting anonymity, no blame culture
8.5	Production and Service Provision
8.5.1	<p>Control of Production and Service Provision</p> <p>Things to consider:</p> <p>Implementation and control of production and service provision including:</p> <ul style="list-style-type: none"> • Availability of documented information that defines product/service characteristics, activities and results to be achieved e.g. works orders, digital product definition data, design definitions, arrangement drawings, component/assembly drawings, key characteristics, process flow charts, parts lists, technical standards, material specifications, process specifications, manufacturing plans, inspection plans, production instructions, process data cards, standard operating procedures, set up diagrams, tooling lists, gage lists, machine tool programs, batch cards, process cards, routers, travelers, control plans, quality plans, test schedules production/service parameters, service instructions, service level agreements, inspection/verification procedures, acceptance criteria • Availability of monitoring and measuring resources e.g. persons, equipment, tooling, gaging, instrumentation, facilities (including environmental controls), machine tool/Coordinate Measuring Machine (CMM) probing/profiling/camera/laser systems, software programs • Implementation of monitoring and measuring activities e.g. <ul style="list-style-type: none"> ○ Inspection/verification planning, identification of inspection/verification points (sequencing) ○ Criteria for acceptance/rejection, specifications, standards, performance parameters, pass/fail limits, acceptance standards, visual aids ○ Equipment requirements (tools, gages, fixtures, machine tools, CMMs etc.) and instructions for use (set up sheets, visual aids, software programs, inspection/verification procedures, operating instructions, standard operating procedures, operator training etc.) ○ Retained measurement results e.g. inspection/verification history cards, CMM reports, pass/fail indicators, test results, verification reports, electronic data capture, FAI (see 8.5.1.3) ○ Sampling e.g. risk assessment, statistical rationale/basis (Acceptance Quality Limits (AQL), Unacceptable Quality Level (UQL), established process capability), sampling plan (product type, features, characteristics, batch/lot size, sample size, inspection levels, type of inspection), defective product (hold, reinspect, reprocess) • Operating infrastructure and environment (see 7.1.3 & 7.1.4) e.g.

	<ul style="list-style-type: none"> ○ Buildings (manufacturing/assembly plants, test facilities, laboratories, service centers, offices etc.) ○ Utilities (electricity, gas, water, compressed air etc.) ○ Equipment (machine tools, jigs, fixtures, tooling, molds, work stations, material handling etc.) ○ IT infrastructure (networks, servers, back up systems, hardware, software programs etc.) ○ Physical environment e.g. space, ergonomics, workplace organization (5S), visual management (layout, zoning, signing etc.) cleanliness, restricted areas, electrostatic discharge, lighting, temperature, humidity, ventilation, noise, FOD prevention, waste reduction (Lean) • Appointment of competent persons (see 7.2) e.g. competency requirements (education, training, skills, knowledge, experience), alignment to role (role profiles, job descriptions, accountability statements, skills matrices), evidence of ability (assessment, evaluation, qualification, requalification) etc. • Validation and revalidation of special processes (see 8.5.1.2) e.g. requirements (standards, specifications, instructions), validation activity (methods, techniques, instructions, data cards, acceptance criteria etc.), approval arrangements (facilities, plant, equipment, process, documents etc.), process monitoring, equipment calibration, person qualification (training, skills, assessment, levels of authorization etc.), periodic revalidation including change control • Prevention of human error e.g. risk assessment, training, competency assessment, qualification, automation, error proofing, mistake proofing, human factors, effective corrective action, read across • Release, delivery and post delivery activities (see 8.5.5 & 8.6) e.g. <ul style="list-style-type: none"> ○ Release/delivery e.g. verification that requirements have been met, customer acceptance testing (if required), product certification/qualification, approval from the relevant authority when requirements have not been met (concession, deviation, waiver etc.), release authorizations, certificates of conformity, release certificates, regulatory certificates (EASA Form 1, FAA 8130 etc.), dispatch documents (consignment notes, delivery notes, shipping notes etc.), export control licenses ○ Post delivery e.g. requirements (organization, customer, statutory, regulatory), dealing with customer feedback (communication, compliments, complaints, issues, problem resolution, satisfaction, warranty, returns, rejections), recall notices, product /service support (queries, training, after sales, maintenance, servicing), collection/analysis of in-service data, lessons learned • Workmanship criteria e.g. standards, samples, artifacts, visual aids, photographs, videos, diagrams, illustrations, comparitors, acceptance/rejection criteria • Accountability for products during production e.g. parts/batch quantities, serialisation, quantity adjustments, (split batches/orders, nonconforming products), MRP updates, control board updates, work tracking/booking, Work In Progress (WIP) monitoring • Critical items e.g. identification, traceability, production/process control, monitoring and measurement arrangements, focus on key
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	<p>characteristics, fixed process approvals, product qualification, change control</p> <ul style="list-style-type: none"> • Methods to measure variable data e.g verification/inspection plans, methods, instructions, techniques, identification of generic tooling, equipment, gages, instrumentation, identification of unique ‘special to product’ equipment, application of machine tool/CMM probing/profiling/camera/laser systems • Planning for in process inspection/verification when verification cannot be performed at a later stage for example prior to processing when features become hidden (coating, painting, surface treatment), prior to assembly when features become inaccessible (sub-assemblies, final assemblies, modules, final product) • Evidence that all operations have been completed e.g. accounting for work via the use of signatures, stamps, electronic work booking etc., or otherwise documented and authorized where completion of an operation is not in accordance with instructions e.g reason, disposition and authorization/approval • Prevention, detection and removal of FOD e.g. <ul style="list-style-type: none"> ○ Prevention (campaigns, signage, briefings, training, bulletins, alerts, risk assessment, control plans, lessons learned etc.) ○ Detection (inspection, instrascopes, boroscopes, x-ray techniques, customer eyes overchecks etc.) ○ Removal (cleaning, purging, disassembly etc.) • Monitoring of utilities and supplies (electricity, gas, water, compressed air, chemical products etc.) that have an impact on the product including; contamination, cleanliness, chemical strength/constituency, pressure, voltage supply etc. and control arrangements e.g. instructions, procedures, frequency of checks, analysis of results, corrections/adjustments • Products released for subsequent production use pending completion of measuring and monitoring activity e.g. identification, communication, document annotation, traceability, authorization to proceed, electronic system (MRP) updates, tracking/recall arrangements
8.5.1.1	<p>Control of Equipment, Tools, and Software Programs</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organisation arrangements to control equipment, tools and software programs used within production including: <ul style="list-style-type: none"> ○ Validate equipment, tools and software programs e.g. instructions, validation criteria, capability studies, production trials, prototypes, test pieces, tooling/equipment proving, component proving, production acceptance, PFMEA, Gage R&R, control charts, production process verification (see 8.5.1.3), acceptance testing, equipment commissioning, verification results, release to production ○ Maintain equipment, tools and software programs e.g. identity, configuration (version/issue control), change control (including authorization), planned maintenance, servicing, calibration, software protection and back up

	<ul style="list-style-type: none"> ○ Storage of equipment and tooling e.g. identity, environment conditions (space, cleanliness, housekeeping, temperature, humidity etc.), preservation and protection (corrosion, deterioration, degradation, damage/loss prevention), asset registers, condition checks, segregation (including equipment and tooling belonging to others – see 8.5.3)
8.5.1.2	<p>Validation and Control of Special Processes</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organisation arrangements for validation and control of special processes (e.g. heat treatment, chemical processing, composites, nonconventional machining, non destructive testing, joining, coating, surface enhancement) including: <ul style="list-style-type: none"> ○ Criteria for process review and approval e.g. technical requirements, verification and validation activity, approval arrangements (process, documents, persons etc.) ○ Conditions to maintain process approval e.g. compliance checks, process oversight, special process audits, requalification of persons, planned maintenance, process monitoring, process surveillance, change control ○ Approval of facilities and equipment e.g. plant (furnaces, machine tools, process lines etc.), equipment, tooling, process consumables, maintenance regime, calibration requirements, test pieces, standards, specifications ○ Qualification of persons e.g. skills matrices, training, oversight, workplace assessment, competency assessment, levels of authorization ○ Methods and procedures e.g. techniques, instructions, data cards, standard operating procedures, diagrams, set up sheets, acceptance criteria ○ Retained documented information (those documents needed to demonstrate that processes have been carried out as planned) e.g. person qualification, process cards, route cards, furnace charts, laboratory reports, test pieces, test results, x-ray film, maintenance records, calibration records, consumable traceability, verification results
8.5.1.3	<p>Production Process Verification</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organisation arrangements to verify that the production process is able to produce products that meet requirements, including for example: <ul style="list-style-type: none"> ○ Capacity/capability studies e.g. determination of producibility, methods, trials, tooling/equipment proving, component proving, production rate readiness, retained documented information (verification results, assessment/analysis reports, data, information etc.) ○ Production Product Approval Process (PPAP) e.g. defined production run, control plan/methods, resources, product/process characteristics, statistical process control, risk assessment (PFMEA), measurement system analysis (Gage R&R), retained

	<p>documented information (timing plan, control plan, verification results, data, information, PPAP file etc.)</p> <ul style="list-style-type: none"> ○ First article inspection (FAI) e.g.: <ul style="list-style-type: none"> ▪ Provision of resources (persons, facilities, equipment etc.) ▪ Selection of a representative FAI item (new product introduction or existing product subject to change) ▪ Identification of the FAI item (Planning for the FAI item, MRP signal for the FAI item, unique identifier etc.) ▪ Verification/inspection activity (requirements, characteristics, features, special processes, materials, software programs, gages, tooling, equipment, drawings, specifications etc.) ▪ Provision for re-verification (requirements not achieved, identified nonconformance, selection of alternative item) • Retained documented information (inspection results, test certificates, certificates of conformity, laboratory reports, gage/equipment traceability, method of manufacture, acceptance etc.)
8.5.2	<p>Identification and Traceability</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organizations use of suitable means to identify products and services e.g. physical part marking, labeling, tags, bar codes, signage, visual indicators, part segregation, lay down areas, storage racks • Identification of the actual versus required configuration of the products/services e.g. MRP system, BOM, parts list, revision status, change control • Control arrangements for acceptance authority media for example: <ul style="list-style-type: none"> ○ Signatures e.g. recognized impression aligned to an authorized signatory list ○ Stamp control e.g. unique identification, stamp issue, scope of authority, stamp withdrawal, register of holders, stamp legibility ○ Electronic signatures e.g. userid, passwords, permissions, restrictions, user profile, scope of authority • Unique identification when traceability is a requirement, together with retained documented information to enable: <ul style="list-style-type: none"> ○ Identification and traceability throughout the product life e.g. life cycle planning, acquisition of raw materials, manufacturing history, serialization, batch control, configuration status, product release, production scrap, maintenance history, in-service history, end of life disposal ○ Traceability of assemblies (components, sub-assemblies, modules, final assemblies etc.), BoM, configuration control, assembly trees, MRP systems ○ Retrieval of production (manufacture, assembly, inspection, test etc.) records e.g. arrangements for storage, whereabouts, location, availability, method of retrieval, permissions, timeliness

8.5.3	<p>Property Belonging to Customers of External Providers</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organizations arrangements relating to property belonging to customers or external providers including for example materials, consumables, parts, tooling, equipment, facilities, intellectual property (standards, specification, drawings, manuals, data, etc.), returnable packaging, products returned for warranty/servicing/investigation • Control of property belonging to customers or external providers e.g. ownership, identification, management of inventory, verification, storage, protection, preservation, restrictions, security, segregation • Retention of documented information and reporting occurrences when property is found to be lost, damaged or unsuitable for use e.g. missing, broken, unserviceable, inventory discrepancies, shelf life expiration, deterioration, illegibility, obsolescence, misconfiguration
8.5.4	<p>Preservation</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization approach towards preserving outputs during production or service provision, including for example: <ul style="list-style-type: none"> ○ Identification e.g. markings, labelling, tags, bar codes, routers, configuration status, traceability indicators ○ General handling e.g. instructions, equipment availability, training, damage prevention ○ Contamination control e.g. instructions, prevention of foreign objects (FOD), protection arrangements (corrosion, deterioration, degradation), damage prevention, prevention of cross contamination (materials, consumables, mistake proofing) ○ Packaging e.g. instructions, materials/equipment availability, training, customer requirements, FOD prevention, re-preservation arrangements (time limitations), reusable containers ○ General storage e.g. stock holding methods, environment controls (temperature, humidity, cleanliness), stock rotation methods such as first in first out (FIFO), inventory control checks, condition checks, shelf life control, access restrictions, security, housekeeping ○ Transmission or transportation e.g. internal/external movements, handling, protection, movement tickets, transport labels, delivery notes, special instructions, electronic transfers, tracking and traceability ○ Protection e.g. instructions, cleaning, use of inhibitors, prevention of loss or damage, materials/equipment availability • Organization approach towards preserving outputs in accordance with specifications and applicable statutory and regulatory requirements, including: <ul style="list-style-type: none"> ○ Cleaning e.g. instructions, sequencing, resources ○ Control of foreign objects (FOD): <ul style="list-style-type: none"> ▪ Prevention e.g. campaigns, signage, briefings, training, bulletins, alerts, risk assessment, control plans, lessons learned,

	<ul style="list-style-type: none"> ▪ Detection e.g. inspection, intrascopes, boroscopes, x-ray techniques, customer eyes overchecks, ▪ Removal e.g. cleaning, purging, disassembly ○ Special handling and storage for sensitive products e.g. storage life, environment controls (temperature, humidity, cleanliness), electrostatic sensitive devices (ESD), clean rooms, access restrictions, security, segregation ○ Marking, labeling, safety warnings and cautions e.g. identification, instructions, notices, advisory's, signage ○ Shelf life control and stock rotation e.g. FIFO, labeling, expiry dates, packaging indicators, inventory control checks, stock control system ○ Special handling and storage for hazardous materials e.g. risk assessment, segregation, access restrictions, security, housekeeping, environment controls (temperature, humidity, cleanliness), personal protective equipment (PPE), records of inventory, control of substances hazardous to health (COSHH)
8.5.5	<p>Post-Delivery Activities</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization determination of post-delivery activities taking into account: <ul style="list-style-type: none"> ○ Statutory and regulatory requirements e.g. legislation, regulations, directives ○ Undesired consequences e.g. risk assessment, impact analysis, failure in service, recall notices, warranty considerations ○ Product/service use e.g. product /service support, lifecycle management, after sales (maintenance, spare parts provision, help line, call centers), technical documentation ○ Customer requirements e.g. contractual arrangements, installation, commissioning, handover, training, customer support ○ Customer feedback e.g. survey results, compliments, complaints, lessons learned, voice of the customer, satisfaction indicators/ratings, returns/rejections, warranty claims ○ Collection and analysis of in-service data e.g. performance, reliability, engineering predictions, lessons learned, operating characteristics, in service events, service intervals, service life, yield rates, service level agreements, service costs ○ Provision of technical documentation e.g. technical publications, operating instructions, maintenance policies, maintenance, repair and overhaul manuals, control arrangements (creation issue, updates, communication, distribution) ○ Control of off-site work (installation, commissioning, maintenance, field support etc.) e.g. liaison, communication, contracts, orders, resources, instructions, training, qualified persons, records of work accomplished, work deviations, control of assets (tooling, equipment, parts, consumables, data) ○ Product/customer support: <ul style="list-style-type: none"> ▪ Queries e.g. points of contact, help line, call centers, frequently asked questions (FAQs)

	<ul style="list-style-type: none"> ▪ Training e.g. provision (classroom, e-learning), manuals, exhibits, webinars ▪ Warranties e.g. contractual obligations, service level agreements ▪ Maintenance e.g. manuals, training, service intervals, resources, spare parts provision, repair schemes, service bulletins ▪ Replacement parts e.g. attrition rates, service history, predicted usage, illustrated parts catalogues, line side stock (standard parts), bill of material (BoM), parts availability, lead times ▪ Resources e.g. people, materials, parts, consumables, information, equipment, financing ▪ Obsolescence e.g. risk management, sustainability, sourcing strategies, source of supply, protect the customer, MRP indicators, service life planning <ul style="list-style-type: none"> • Organization arrangements for dealing with problems detected after delivery e.g. reaction to the problem, containment, correction, investigation, problem resolution, corrective action, read across, communication, reporting, lessons learned
8.5.6	<p>Control of Changes</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Organization approach towards the review and control of production/service change to ensure continuing conformity with requirements taking into account: <ul style="list-style-type: none"> ○ Reason for change (planned and unplanned) ○ Temporary or permanent change ○ Review, assessment and evaluation of the change proposal ○ Verification or validation of the change prior to implementation ○ Approval of the change by the appropriate authority (including the customer/regulator where required) ○ Implementation of the change (e.g. implementation plan, revised documented information, communication) ○ Confirmation that the change has been incorporated, including updates to the QMS as required ○ Monitoring of effectiveness of the change • Changes to production and service provision can include, changes to: <ul style="list-style-type: none"> ○ Customer/regulatory requirements ○ Source and process methods ○ Software used to control operational activity (e.g. machine tool/inspection/test programs) ○ Drawings, diagrams, illustrations ○ Process/work instructions ○ Machines, tools, jigs, fixtures, equipment, gages

	<ul style="list-style-type: none"> ○ Materials, consumables ○ Maintenance regimes ○ Service intervals ○ Authorized person(s) ○ Special process parameters ○ End user documents (instructions, technical publications etc.) ○ Handling, storage, packaging, preservation requirements ○ Operator/end user training ○ Environmental controls <ul style="list-style-type: none"> • The identification of the person(s) authorizing the change such as: name, signature, role, user identification, stamp impression, etc., together with the scope, delegations and authority status relating to the change(s) being made. • The retention of documented information relating to the authorized change such as change notices, alteration requests, coordination memos, revised instructions, quality plan, deviation requests, verification/validation results, review minutes, implementation plan, together with any actions arising from the identified change.
8.6	<p>Release of Products and Services</p> <p>Things to consider:</p> <ul style="list-style-type: none"> • Implementation of the organizations planned arrangements at appropriate stages to verify that product and service requirements have been met. Planned arrangements can include design verification/validation (modelling, simulations, experiments, trials, prototypes, functional testing, performance testing), inspection (stage, final, first article), examination (destructive/non-destructive), Production Part Approval Process (PPAP), customer acceptance testing, product certification/qualification, third party qualification (regulator, society, independent body etc.), • Ensuring that the planned arrangements have been satisfactorily completed prior to release of the product or service, or obtaining approval from the relevant (internal/external) authority or customer when planned arrangements have not been completed prior to release e.g. concession, deviation, waiver, contract amendment, dispensation, release endorsement • Records to provide evidence that acceptance criteria has been met e.g. certificate of conformity, release certificate, regulatory certificate (EASA Form 1, FAA 8130 etc.) • Traceability to the person(s) authorizing the release such as name, authorized signatories, user identification, stamp impression etc., including their authority status (release signatory, certifying staff, scope of authorization etc.) • Records to provide evidence that product qualification meets defined requirements e.g. inspection history, test reports,

	<p>verification/validation reports, acceptance documents, qualification certificates</p> <ul style="list-style-type: none"> Accompanying documentation at the point of delivery e.g. certificate of conformity, release certificate, regulatory certificate (EASA Form 1, FAA 8130 etc.), despatch documents (consignment notes, delivery notes, shipping notes etc.) export control licences, user instructions, handling instructions, maintenance instructions, log books, technical publications
8.7	Control of Nonconforming Outputs
8.7.1	<p>Things to consider:</p> <ul style="list-style-type: none"> Arrangements for controlling nonconforming outputs, including products, services or processes identified internally or externally including: <ul style="list-style-type: none"> Organizations maintained documented information (see 4.4.2) that defines the nonconformity control process (e.g. documented procedure) including: <ul style="list-style-type: none"> Responsibility and authority for the review and disposition of nonconforming outputs e.g. Authorized signatories, nonconformance control authorities, delegated technical authorities, Material Review Board (MRB), customer The process for approving persons who disposition nonconforming outputs e.g. organization role, knowledge, experience, demonstrated competence, qualification, requalification, including scope of authority (type, product, project, service etc.) Taking action to contain the effect of the nonconformity such as reaction/response times, impact/risk assessment, stop and fix, read across to same or similar products, services and processes that may be impacted (new product introduction, work in progress, disposition of service, stock held in storage, product held by external providers, product in transit, product already delivered to the customer etc.) The requirements for timely reporting of the nonconformity to relevant interested parties relating to products or services already delivered e.g. respective timescale for reporting, responsibility for reporting, method of reporting (internal/external communication, notifications, corrective action reports, recall notices, safety alert reports, mandatory occurrence reports, service bulletins, advisory's etc.), acknowledgement of report(s) The arrangements for defining corrective actions for nonconforming outputs detected after delivery (see 10.2) i.e. reaction to the nonconformity, evaluation of necessary action(s), implementation and monitoring of identified action(s), review of effectiveness and sustainment of action(s) taken Implementation of the organizations documented nonconformity control process (as above) to ensure that appropriate action is taken according to the nature of the nonconformity Organization provision for dealing with nonconforming outputs including:

	<ul style="list-style-type: none"> ▪ Corrections e.g. enable rework (correction labels, updated instructions etc.) to achieve conformity, including verification of the conforming status after correction (checking, inspection, testing etc.) ▪ Segregation e.g. physical separation of nonconforming products, use of dedicated holding areas (floor space, racking, quarantine bonds, cages), identification to show nonconforming status (labels, markings, tags, annotation of documented information, electronic system (MRP) updates) ▪ Containment e.g. reaction/response times, impact/risk assessment, stop and fix, communication, read across to same or similar products, services and processes ▪ Return or suspension of outputs e.g., stop shipment, suspend service, product recall, freeze inventory, block stock, hold instruction ▪ Informing the customer e.g. communication, notifications, alerts, bulletins, advisory's ▪ Acceptance under authorized concession (including the customer when required) e.g. concession, waiver, deviation, production permit, service alleviation ○ Implementation of use-as-is (accepted deviation as identified), or repair (accepted restoration to a useable condition) in accordance with a disposition (e.g. concession, waiver, deviation): <ul style="list-style-type: none"> ▪ Approved by an authorized design responsible representative within the organization, or ▪ Approved by person(s) with appropriate delegated authority, and ▪ Authorized by the customer if the nonconformity has an impact on the contract requirements ○ Control of products dispositioned as scrap including: <ul style="list-style-type: none"> ▪ Conspicuous marking (e.g. scrap labels, tags, signs, paint) and permanent markings (e.g. removal of product identity, applying scrap identification status), or ▪ Positive control (e.g. segregation, dedicated holding areas (floor space, racking, quarantine bonds, cages etc.), annotation of documented information, electronic system (MRP) updates ▪ Physically rendered unusable by the organization or a controlled external provider (e.g. product destruction, removal of key features, product deformation, product mutilation, conversion back to raw material (revert, recycling) and control of any inherent hazardous material/substances (as required) ○ Control of counterfeit or suspect counterfeit parts (see 8.1.4), to prevent re-entry into the supply chain e.g. labeling, marking, segregation, quarantine, containment, disposition, annotation of documented information, electronic system (MRP) updates
8.7.2	<p>Things to consider:</p> <ul style="list-style-type: none"> • Organization arrangements for retaining documented information that:

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| | <ul style="list-style-type: none">○ Describes the nonconformity e.g. statements, illustrations, reports, objective evidence○ Describes actions taken e.g. dispositions relating to correction, concession, scrap○ Describes any concessions obtained e.g. accepted concession, waiver, deviation, production permit, service alleviation○ Identifies the deciding authority e.g. authorized signatories, nonconformance control authorities, delegated technical authorities, Material Review Board (MRB), customer |
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Clause #	Considerations
9.	PERFORMANCE EVALUATION
9.1	Monitoring, Measurement, Analysis and Evaluation
9.1.1	<p>General Things to consider:</p> <ul style="list-style-type: none"> • Identification of “what” needs to be monitored and measured, for example: <ul style="list-style-type: none"> ○ QMS and process performance e.g. achievement of quality objectives, process performance indicators, target setting, audit results (conformity/non-conformity, effectiveness), trends ○ Operational performance e.g. product/service conformity, production yield, right first time, parts per million (PPM), defects per unit (DPU), product characteristics, process parameters, process capability, identification of waste, on time delivery, queuing times, resolution of customer issues, service availability, in-service reliability, average service time ○ Delivery of projects to plan e.g. spend against budget, milestone achievement ○ External provider performance, e.g. product/service conformity, on time delivery, approval ratings, returns/rejections, invoice queries ○ Customer performance e.g. survey results, satisfaction indicators/ratings, compliments, complaint profile, returns/rejections, warranty claims, invoice queries ○ Management of risk and opportunities to prevent and reduce undesired effects, enhance desired effects and achieve improvement, e.g. identification, assessment, treatment • Determination of the “methods” used for monitoring, measurement, analysis and evaluation, for example: <ul style="list-style-type: none"> ○ Data capture instructions, e.g. procedures, quality plans, data collection sheets, data acquisition software, sampling techniques, frequency ○ Statistical process control (SPC) including run charts, histograms, control charts, Pareto diagrams, scatter diagrams, cause and effect (fishbone) diagrams, glyph/radar charts, design of experiments ○ Project earned value, including cost performance index (CPI) and schedule performance index (SPI) ○ Management of risk, e.g. risk avoidance, risk elimination, taking risk, risk treatment, risk transfer and taking risk to pursue opportunities ○ Performance governance, e.g. management review, process reviews/councils, performance reports, score cards, flight

	decks/dashboards
9.1.2	<p>Customer Satisfaction Things to consider:</p> <ul style="list-style-type: none"> • Determination of the “methods” used for obtaining, monitoring and reviewing customer perception, for example: <ul style="list-style-type: none"> ○ Customer surveys/questionnaires conducted by the organization itself or via an independent research agency. NOTE: surveys may relate to all customers or a representative sample and the frequency may vary according to the relationship ○ Customer feedback relating to delivered products and services, e.g. product/service conformity, on time delivery, report cards, satisfaction indicators/ratings, compliments ○ Customer communication, e.g. face to face meetings, telephone calls, use of field operatives (installation/service personnel), day to day enquires (via internal personnel), use of social media (websites, message boards, on-line help), reports from dealers, distributors, integrators ○ Complaint profile including rejections, returns, warranty claims, invoice queries, corrective action requests, ○ Market share analysis and evaluation of repeat business • Arrangements for developing and implementing plans to improve customer satisfaction including: analysis of results and trends, input to management review, addressing identified product/service deficiencies (including improvements to the QMS), assessing the effectiveness of action taken
9.1.3	<p>Analysis and Evaluation Things to consider:</p> <ul style="list-style-type: none"> • Analysis of appropriate data arising from monitoring and measurement (see 9.1.1) in order to evaluate: <ul style="list-style-type: none"> ○ QMS and process performance e.g. achievement of quality objectives, process performance indicators, target setting, audit results (conformity/non-conformity, effectiveness), trends ○ Operational performance, e.g. product/service conformity, production yield, right first time, parts per million (PPM), defects per unit (DPU), product characteristics, process parameters, process capability, identification of waste, on time delivery, queuing times, resolution of customer issues, service availability, in-service reliability, average service time ○ External provider performance, e.g. product/service conformity, on time delivery, approval ratings, returns/rejections, invoice queries ○ Customer performance, e.g. survey results, satisfaction indicators/ratings, compliments, complaint profile, returns/rejections, warranty claims, invoice queries ○ If planning has been implemented effectively, e.g. actions to address risks and opportunities, achievement of quality objectives,

	<p>planning of changes and operational planning</p> <ul style="list-style-type: none"> ○ Information on product and service problems reported by external sources, e.g. alerts, advisories, directives, service bulletins ○ Delivery of projects to plan, e.g. spend against budget, milestone delivery, earned value, cost performance index (CPI), schedule performance index (SPI) ○ Effectiveness of actions taken to address risks and opportunities, e.g. risk assessment, risk treatment, residual risk values, performance trends, adoption of new practices, launching new products/services, winning new customers <ul style="list-style-type: none"> • Using the documented output of analysis and evaluation, e.g. trend analysis and reports as an input to management review (see 9.3.2) to enable the organization to determine the performance and effectiveness of the QMS and identify improvements <p>NOTE: Analysis of the data can be undertaken using statistical techniques to help break down the information and present it in a format that allows a determination to be made of whether actions are needed.</p>
9.2	Internal Audit
9.2.1	<p>Things to consider:</p> <ul style="list-style-type: none"> • Organization arrangements for conducting internal audits at planned intervals to demonstrate that the QMS conforms to: <ul style="list-style-type: none"> ○ The organizations own requirements, e.g. policies, processes, procedures, instructions, specifications ○ Customer requirements, e.g. flowed down by contract ○ Statutory and regulatory requirements, e.g. legislation, regulations, directives ○ Applicable external standards (including 9100) • Organization approach to knowing how well the QMS has been effectively implemented and maintained for example by: <ul style="list-style-type: none"> ○ Obtaining audit results ○ Reporting audit performance ○ Monitoring trends, e.g. process strengths and weakness, repeat audit findings, acknowledged improvement
9.2.2	<p>Things to consider:</p> <ul style="list-style-type: none"> • Publication of an audit program, or a number of audit programs dependant upon the size and complexity of the organization, including the identification (title, scope, criteria) and frequency of each audit, e.g. monthly, quarterly, annually • Organization methods used for undertaking audits for example audit selection, audit planning, audit conduct, audit reporting, corrective action, close out, process measures, e.g. audit delivery against the schedule, time to respond to a nonconformity, time to correct a nonconformity • Application of risk based thinking to select audits and their frequency for example consideration of:

	<ul style="list-style-type: none"> ○ Processes that are critical to product and service quality ○ Complex processes that require close monitoring and control to ensure conformity ○ Balance across operational and non operational processes ○ Processes that utilize qualified personnel ○ Activities or processes that occur across multiple locations ○ Processes impacted by human factors ○ Introduction of new or changed processes ○ Changes affecting the organization ○ Statutory and regulatory issues ○ Process performance, e.g. process conformity/nonconformity, escapes to the customer, complaints, previous internal/external audit results, identified risk (see 6.1 and 8.1.1) <ul style="list-style-type: none"> • Definition of the criteria, (policy, process, procedure, requirements) and scope (extent, boundaries, physical location, product line, facility, department, activities, duration) for each identified audit • Management commitment, authorization and control of the audit program(s) from initial issue, together with the identification and reason(s) for change • Conducting of audits on time in accordance with the schedule (previous and current periods) • Auditor resources including training/qualification and selection of auditors to ensure independence of the area/process being audited • Collection of audit evidence and reporting of audit findings including correct grading of findings (conformity, nonconformity, strengths, opportunities for improvement) • Routine reporting of audit results to the relevant management (circulation of audit report, closing meeting/outbriefs, audit performance metrics), including an input to Management Review (see 9.3.2) • Timely undertaking of corrections (fix the issue) and corrective actions (prevent recurrence) by the organization • Follow up by the auditor to ensure effective and timely implementation of correction and corrective action • Retention of documented information to show that that the audit program has been effectively implemented (audit program, audit plans, audit reports, questionnaires, audit evidence, corrective action, audit close out, auditor qualification, audit performance metrics) <p>NOTE: Audit information can be in hard copy format, or managed within an IT system</p>
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9.3	Management Review
9.3.1	<p>General Things to consider:</p> <ul style="list-style-type: none"> • Top management arrangements for reviewing the QMS at planned intervals to ensure continuing: <ul style="list-style-type: none"> ○ Suitability (fit for purpose) ○ Adequacy (meets the needs of the organization) ○ Effectiveness (achieves intended results) • Frequency of review, e.g. monthly, quarterly, six monthly, annual • Stand alone review or combined with other business activities, e.g. strategic planning, business planning, operations meetings, process reviews/councils, functional reviews • Representation at the review, e.g. top management, functional management, line management, process owners, process champions, lead process users, action owners
9.3.2	<p>Management Review Inputs Things to consider:</p> <ul style="list-style-type: none"> • Status of actions (open/closed) from previous meeting(s), ageing profile of open actions, e.g. 3 months, 6 months, 12 months, greater than 1 year • Changes arising from monitoring internal/external issues that are relevant to the QMS (see 4.1) • Identification and evaluation of changes to internal/external requirements, e.g. policies, processes, procedures, methods, instructions, contracts, regulation, legislation, that impact the QMS • QMS performance and effectiveness including: <ul style="list-style-type: none"> ○ Customer satisfaction (see 9.1.2) and feedback from other interested parties, e.g. report cards, indicators, ratings, complaints, compliments, media reports ○ Achievement of quality objectives (see 6.2), including status of planned versus actual achievement ○ Organization and external provider process performance and product/service conformity (see 4.4, 8.4 and 8.6), e.g. flight decks, dashboards, scorecards, performance indicators, performance trends, right first time, on time delivery, escapes to the customer, complaint profile, returns/rejections ○ Nonconformity and corrective action (see 10.2) e.g. Pareto of nonconformity by type, process, area, root cause etc., read across to other parts of the organization or to external parties, update of risks (see 6.1 and 8.1.1), status of corrective action implementation

	<ul style="list-style-type: none"> ○ Audit results (see 9.2), e.g. achievement of the audit program(s), areas of good practice, nonconformity profile (number, type, process, area, significance), status of corrective action, audit close out, external audit findings ○ Adequacy of internal resources and external providers (see 7.1) including people (number, roles, competency etc.), infrastructure (buildings, equipment, systems, transport etc.), working environment (physical and human factors, monitoring and measuring equipment (availability, fit for purpose, maintained) ○ Effectiveness of actions taken to address risks and opportunities (see 6.1), e.g. risk profile, risk register(s), status of open/closed actions, ageing profile of open actions, evaluation of effectiveness (enhance desirable effects, prevent, reduce undesired effects, demonstrated improvement) ○ Identification of opportunities for improvement (see 10.1), corrective action, good practice, best practice, innovation, lessons learned etc., including read across the organization and to external providers
9.3.3	<p>Management Review Outputs Things to consider:</p> <ul style="list-style-type: none"> • Decisions and actions relating to: <ul style="list-style-type: none"> ○ Opportunities for improvement (see 10.1) e.g. read across and implementation of corrective action, good practice, best practice, innovation, lessons learned etc. ○ Changes to the QMS (see 6.3), e.g. policies, processes, procedures, methods, instructions ○ Resource needs (see 7.1), e.g. people (number, roles, training), infrastructure (buildings, equipment, systems, transport), working environment (physical and human factors), monitoring and measuring equipment (availability, fit for purpose, maintained) ○ Identified risks (see 6.1 and 8.1.1), e.g. adding new risks at an organization or operational level to the appropriate register(s) and the assignment of responsibility and treatment • Documented evidence of the review, e.g. attendance, agenda, presentations, meeting minutes, actions (list, owners, timescale), reports • Retention of documented information of the review and communication of the relevant content across the organization (see 7.4)

Clause #	Considerations
10.	IMPROVEMENT
10.1	<p>General Things to consider:</p> <ul style="list-style-type: none"> • Organization arrangements for identifying opportunities for improvement and taking action in order to: <ul style="list-style-type: none"> ○ Achieve intended results e.g. using analysis and trending of organizational performance (see 9.1.3) ○ Meet customer requirements and expectations e.g. understanding contractual arrangements and implied customer expectations ○ Enhance customer satisfaction e.g. using satisfaction indicators/ratings, complaints profile, returns/rejections, warranty claims (see 9.1.2) • Organization approach towards undertaking improvement, for example: <ul style="list-style-type: none"> ○ Focus on improving products and services, including future needs and expectations, e.g. investment in latest technology and innovation, improving reliability, improving yield, reducing cost, improving on-time delivery ○ Correcting, preventing and reducing undesired effects, e.g. investigating root cause, preventing escapes to the customer, acting on customer feedback and/or in service reports ○ Improving the performance and effectiveness of the QMS, e.g. acting on process performance results, understanding audit findings, reducing waste, process re-engineering, structural re-organization, promoting breakthrough projects
10.2	Nonconformity and Corrective Action
10.2.1	<p>Things to consider:</p> <ul style="list-style-type: none"> • Organizations maintained documented information (see 4.4.2) that defines the nonconformity and corrective action management processes, e.g. documented procedure • Organizations reaction to nonconformities when they arise from sources such as nonconforming product (identified during manufacture or post delivery), customer complaints, audit findings, warranty claims, etc. including: <ul style="list-style-type: none"> ○ Taking action to control and correct the nonconformity, e.g. understanding the problem, applying immediate containment (protect the customer), undertaking correction and corrective action. ○ Dealing with the consequences, e.g. communication within the organization, contacting interested parties if required (customers, regulators, external providers), applying risk assessment

	<ul style="list-style-type: none"> • Organizations evaluation of the need to take action to eliminate the cause of the nonconformity to ensure it doesn't exist elsewhere and to prevent recurrence by: <ul style="list-style-type: none"> ○ Reviewing and analyzing the nonconformity e.g. describing the problem (who, what, when, where, how, how many), assigning a problem owner, launching an investigation, collecting information, engagement with others with product/process knowledge ○ Using appropriate methodologies, e.g. root cause analysis, 5 Whys, Ishikawa (cause and effect diagram), Pareto charts, process flow diagram, 8 disciplines of problem solving (8d), 9 steps to problem solving (9s), Failure Mode and Effect Analysis (FMEA) etc. to determine the cause(s) of the nonconformity (including those related to Human Factors) and extent of the action(s) needed, based upon the potential effect of the nonconformity ○ Determining if similar nonconformities exist or could occur elsewhere e.g. communication within and outside the organization (as appropriate), verification and quarantine (if required) of other products that could potentially be impacted (work in progress, product held by external providers, stock held in storage, product already delivered to the customer, product in transit, product recall) • Implementation and monitoring of identified action(s) through the use of action plan(s), owner(s), resources, tasks, timescales, management review etc. to ensure: <ul style="list-style-type: none"> ○ Timely corrective action is taken within the organization and any external provider(s) where necessary ○ Further action is taken when timely and effective corrective action is not achieved • Reviewing the effectiveness of corrective action(s) taken, e.g. observing the performance of the process, reviewing documented information, conducting compliance checks, or audits to ensure: <ul style="list-style-type: none"> ○ The root cause was addressed ○ That no other issues were caused by the corrective action <p>NOTE: Establishing the effectiveness of corrective action may take an appropriate amount of time after corrective action has been implemented, to ensure that it has been sustained</p> <ul style="list-style-type: none"> • Conducting a follow up to ensure sustainment: <ul style="list-style-type: none"> ○ Planning is updated if necessary (see 6.1) to capture any identified risks and opportunities that were not previously considered ○ Changes are incorporated into the QMS if necessary, (process documents, procedures, work instructions, control plan, service plan, drawings, resources etc.)
10.2.2	Things to consider:

	<ul style="list-style-type: none"> • Organization arrangements for retaining documented information to show the: <ul style="list-style-type: none"> ○ Nature of the nonconformities, e.g. source, type, quantity, frequency, severity ○ Action(s) taken, e.g. corrective action documents, action trackers, management review outputs, lessons learned, risk registers, on-line systems ○ Results of corrective action, e.g. open versus closed, achievement of milestones, performance measures (time to close, problem recurrence, cost of non quality)
10.3	<p>Continual Improvement Things to consider:</p> <ul style="list-style-type: none"> • Organization arrangements for continually improving the suitability, adequacy and effectiveness of the QMS considering the: <ul style="list-style-type: none"> ○ Results of Analysis and Evaluation (see 9.1.3) ○ Output from Management Review (see 9.3.3) • Determination of improvement activity based upon: <ul style="list-style-type: none"> ○ External drivers, e.g. regulatory changes, legislation, market expectations, competitor activity, interested party perceptions, customer satisfaction, environmental impact, benchmarking of best practice ○ Internal drivers, e.g. business strategy, achievement of objectives, problem resolution, business/process performance, process capability, cost reduction, reduce leadtime, right-first-time, on-time delivery, improved efficiency, lessons learned, reduce variation, risk reduction, operational budgets, prioritization, employee suggestions • Use of appropriate methodologies and tools to undertake continual improvement including for example: <ul style="list-style-type: none"> ○ Plan, Do, Check, Act (PDCA) approach to control and continuously improve processes and products: <ul style="list-style-type: none"> ▪ Plan: define the problem, collect relevant information/data, understand current performance, determine the root cause, set improvement objectives/target, decide on timescale, determine resources and budget ▪ Do: develop and implement a solution, introduce a form of measurement to determine the effectiveness of the solution, monitor progress, review against the plan and make any necessary adjustments ▪ Check: measure performance, compare outcome against expectations, verify to confirm expected results have been achieved ▪ Act: document the results, communicate the outcome, make recommendations based on results achieved, assess and repeat the cycle if required, update the systems and documentation to sustain the improvement ○ Lean approach to improve cycle time, optimize resources and elimination of waste using such techniques as: workplace organization (5S), visual factory, value stream mapping, kaizen activity, Overall Equipment Effectiveness (OEE), Total Productive

	<p>Maintenance (TPM), takt time, Just-in-Time (JiT), mistake proofing etc.</p> <ul style="list-style-type: none"> ○ Six-Sigma approach to improve process capability, removing causes of defects and reduce variation using such techniques as: the Define, Measure, Analyze, Improve, Control (DMAIC) model, Define, Measure, Analyze, Design, Verify (DMADV) model, process mapping, Supplier, Input, Process, Output, Customer (SIPOC) diagram, cause and effect (fishbone) diagrams, Measurement Systems Analysis (MSA), gage R&R, run charts, histograms, control charts, Pareto diagrams, scatter diagrams, , glyph/radar charts, Design of Experiments (DoE), Failure Mode and Effects Analysis (FMEA) etc. • Organization arrangements for monitoring the implementation of improvement activities and the effectiveness of the results, e.g. dashboards, flight decks, registers, milestone charts, action trackers, performance indexes and trends, benefits capture, on-line systems, formal reporting, input to management review
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4.0 Change Control

Revision	Detail	Date
1.0	Initial issue to support implementation of 9100:2016 including sections 1, 2 and 3 (clauses 4, 5, 6, 9, 10)	15 Dec 2016
1.1	Section 3 updated with new content for clauses 7.1, 7.2, 7.3, 7.4, 7.5, 8.1, 8.2 and 8.3.	13 Apr 2017
2.0	Section 3 updated with new content for clauses 8.4, 8.5, 8.6, 8.7, content page added and whole document updated to landscape version	20 Jul 2017
2.1	Document title changed to 'Evaluation Guidance Material' and IAQG copy write statement added	17 Oct 2017